

PCT

WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau



15

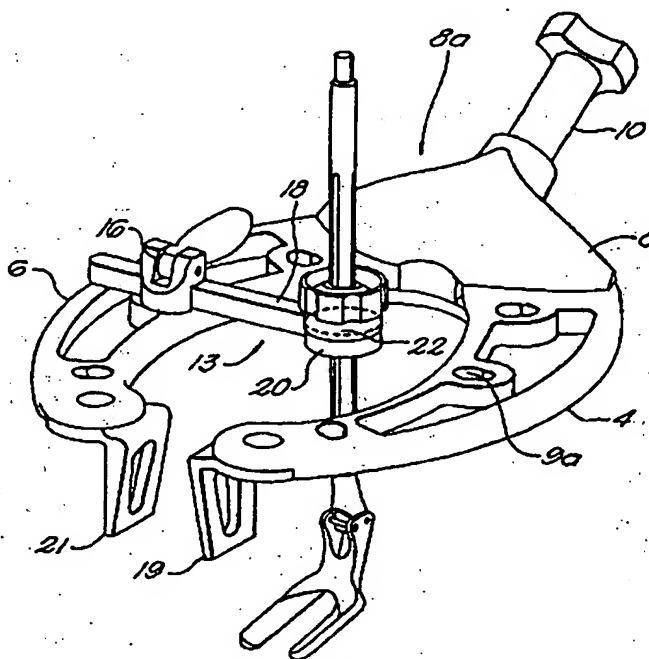
INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61B 17/02, 19/00		A1	(11) International Publication Number: WO 98/27869
			(43) International Publication Date: 2 July 1998 (02.07.98)
(21) International Application Number: PCT/US97/23612		(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CZ, DE, DK, EE, ES, FI, GB, GE, GH, HU, ID, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).	
(22) International Filing Date: 19 December 1997 (19.12.97)			
(30) Priority Data: 08/773,485 23 December 1996 (23.12.96) US			
(71) Applicants: UNIVERSITY OF MASSACHUSETTS [US/US]; 18 Tremont Street, Boston, MA 02108 (US). SMITH & NEPHEW, INC. [US/US]; 160 Dascomb Road, Andover, MA 01810 (US).			
(72) Inventors: SIKORA, George; 3 Barnboard Road, Mansfield, MA 02048 (US). BEANE, Richard; 52 Burr Road, Hingham, MA 02043 (US). STAHL, Russell, F.; 55-2 Commons Drive, Shrewsbury, MA 01545 (US). SOLLER, Babs, R.; 15 Franklin Circle, Northboro, MA 01532 (US). EK, Steven, W.; 59 Bolton Woods Way, Bolton, MA 01740 (US). McCARTHY, Gary; 10 Sauckett Avenue, East Bridgewater, MA 02333 (US). DAVIS, Bill; 6 White Horse Road, Hingham, MA 02043 (US). VERDURA, Javier; 1567 Milford Creek Lane, Marietta, GA 30060 (US).		Published With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.	
(74) Agents: LIEPMANN, W., Hugo et al.; Lahive & Cockfield, LLP, 28 State Street, Boston, MA 02109 (US).			

(54) Title: MINIMALLY INVASIVE SURGICAL APPARATUS AND METHOD

(57) Abstract

The present invention encompasses novel tools and a tool-holding retractor assembly. The retractor assembly spreads an incision and holds the incision open. At least one extension device, having a tool holder on one end, attaches to the assembly. The holder includes a selectively locking multi-axis adjustable mounting element adapted to grip a tool shaft. The mounting element acts as a universal mounting providing rotational and sliding movement of the tool shaft. The extension device adjusts to position the tool holder peripherally of the surgical field. Once the retractor is placed, the extension device provides full access to regions below the incision. The extension device allows the surgeon to chose the insertion point and insertion angle of the tool shaft.



BEST AVAILABLE COPY

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav Republic of Macedonia	TM	Turkmenistan
BF	Burkina Faso	GR	Greece	ML	Mali	TR	Turkey
BG	Bulgaria	HU	Hungary	MN	Mongolia	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MR	Mauritania	UA	Ukraine
BR	Brazil	IL	Israel	MW	Malawi	UG	Uganda
BY	Belarus	IS	Iceland	MX	Mexico	US	United States of America
CA	Canada	IT	Italy	NE	Niger	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NL	Netherlands	VN	Viet Nam
CG	Congo	KE	Kenya	NO	Norway	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NZ	New Zealand	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	PL	Poland		
CM	Cameroon	KR	Republic of Korea	PT	Portugal		
CN	China	KZ	Kazakhstan	RO	Romania		
CU	Cuba	LC	Saint Lucia	RU	Russian Federation		
CZ	Czech Republic	LI	Liechtenstein	SD	Sudan		
DE	Germany	LK	Sri Lanka	SE	Sweden		
DK	Denmark	LR	Liberia	SG	Singapore		
EE	Estonia						

MINIMALLY INVASIVE SURGICAL APPARATUS AND METHOD

Background

Minimally invasive or video assisted surgical procedures are being developed to
5 reduce trauma, surgically induced complications, and costs associated with a lengthened
hospital stay. One common, and costly operative procedure in the US is coronary artery
bypass grafting (CABG), therefore, considerable attention has been given to establishing
procedures for performing CABG surgery as a minimally invasive operation. Two basic
approaches are currently being investigated by cardiac surgeons:

10 CABG (and other heart) operations on an arrested heart with percutaneous
cardiopulmonary bypass (CPB); and

CABG procedures on a *beating heart without* cardiopulmonary bypass.

There are certain advantages to the second approach in that CPB is known to be
associated with some complications that can occur in open heart surgery. However,
15 surgery on a beating heart is technically difficult, especially when performed through a
small incision between ribs. Thus, there is a need to facilitate CABG surgery on a
beating heart performed through an incision. A common CABG procedure is a graft
between the left internal mammary artery (LIMA) and the left anterior descending
(LAD) coronary artery. While several other coronary arteries may be treated by CABG,
20 and other vessels can be grafted to the LAD, a LIMA-LAD graft will be discussed
below as illustrative of the invention.

To access and work on the LAD while the heart is beating requires clamping or
immobilizing at least a portion of the heart. Previously surgeons have used hand held
surgical devices for limiting some motion of the heart. However, these devices are not
25 particularly effective in limiting the motion of the heart and they require that an assistant
place at least one hand near the surgical site. Other devices provide retractor assemblies
for retracting tissue around a surgical opening to provide a sufficiently large access for
surgery, and further provide mechanisms whereby retractor blades, used to pull back
organs or tissue, or other surgical implements are attached to the retractor assembly.
30 The retractor itself generally consists of a frame which fits or is assembled about a
perimeter of the opening.

However, the implements of these assemblies do not have complete access to the
surgical field. In other words, the mechanisms which attach the implements to the
retractor assemblies allow only limited freedom of movement. Thus, if a surgeon uses
35 such a configuration and adds further specialized surgical implements, the limited
freedom of movement might complicate the surgery. For example, when a surgeon
creates an incision for heart surgery and places a retractor, the heart is still covered with

- 2 -

the pericardial membrane, an opaque tissue, and the surgeon can not clearly determine the location of the artery of interest at this point in the surgery. Thus, if the surgeon wants to attach a device to the retractor to locally limit the motion of the heart, the surgeon is required to estimate the location of the artery of interest and place the retractor and device accordingly.

Upon removing the opaque tissue and discovering the actual location of the cardiac artery, it may be necessary to reposition both the surgical implements and the retractor. To disassemble and re-configure a retractor and associated surgical implements takes time, and puts the patient at risk of complications.

Therefore, there is a need for a more versatile retractor assembly with attached surgical implements that have greater and more flexible access to the surgical field. There is also a need for surgical implements that are more effective in limiting the motion of the heart and do not require an assistant to place a hand near the surgical site.

15 Summary of the Present Invention

It is an object of this invention to provide a surgical retractor apparatus, and a related method, for holding an incision open so that a surgeon can operate on tissue under direct vision.

Another object of this invention is to provide tools and methods for use with the above retractor apparatus which will stop blood flow temporarily in selected arteries, to enable the surgeon to visualize the surgical site.

Another object of this invention is to provide tools and methods for use with the above retractor apparatus which limit the motion of a patient's heart locally, leaving the remainder of the heart to beat normally.

Another object of the invention is provide further tools and methods for use with the above retractor apparatus to assist in a surgical procedure.

The present invention encompasses novel tools and a tool-holding retractor assembly. The retractor assembly spreads an incision and holds the incision open. At least one extension device, having a tool holder on one end, attaches to the assembly. The holder includes a selectively locking multi-axis adjustable mounting element adapted to grip a tool shaft. The mounting element acts as a universal mounting providing rotational and sliding movement of the tool shaft, while the extension device adjusts to position the tool holder peripherally of the surgical field. Once the retractor is placed, the extension device provides full access to regions below the incision, so the retractor need not be re-positioned for the surgeon to position a tool at a chosen site in the surgical field. The extension device allows the surgeon to chose the insertion point

- 3 -

and positioning angle of the tool shaft. Furthermore, the tools are designed for insertion over the edge of an incision.

Brief Description of the Drawings

5 FIG. 1 is an illustration of a supine patient with a retractor according to the present invention mounted at an incision;

10 FIG. 2A is a perspective view from above of a retractor and an extension device with an attached tool, according to a preferred embodiment of the invention;

FIG. 2B is a top plan view of the retractor and extension device of FIG. 2A;

FIG. 2C is a back side view of the retractor and extension device of FIG. 2A;

15 FIG. 3A is a perspective view from above of an opening mechanism for the retractor of FIG. 2A;

FIG. 3B is an exploded view of the opening mechanism of FIG. 3A;

20 FIG. 4 is a cutaway view of a disposable light wand for use with the retractor depicted in FIG. 2B;

25 FIG. 5 is an exploded view of the cam lock clamp assembly depicted in FIGS. 2A and 2B;

FIG. 6 is a perspective view from above of a positioning arm having a tool holder on one end and an attached tool for use with the retractor depicted in FIG. 2A;

30 FIG. 7 is an exploded view of a ball and socket joint mounting element for use with the extension device of FIG. 2A;

FIG. 8A is an exploded view of a tool shaft pivotly linked to an end-effector;

35 FIG. 8B is a perspective view from above of a tool shaft pivotly linked to an end-effector;

FIGS. 9A-1, 9A-2, 9A-3, 9A-4, 9A-5, 9A-6, 9A-7, and 9A-8 are a series of perspectives of a U-shaped end-effector;

- 4 -

FIG. 9B is a perspective view of a U-shaped end-effector with microtraumatic surfaces;

5 FIG. 9C is a cross-sectional view of the end effector of FIG. 9B viewed from a plane parallel to line B-B of FIG. 9B;

FIG. 10A is an exploded view of a tool holder with an attached tool, the tool comprising a tool shaft and an end-effector; a series of end-effectors for use with the tool
10 shaft are also depicted;

FIG. 10B shows a series of tools for use with the tool holder of FIG 10A;

FIGS. 11A, 11B and 11C are a top plan view of a closed retractor, a perspective
15 view from above of an open retractor, and a top plan view of an open retractor, respectively;

FIGS. 12A, 12B, and 12C are a perspective view from above of an extension device attached to a retractor, a cross-section view of a clamp assembly, and a cross-
20 section view of a retractor frame member and retractor blade, respectively;

FIG. 13 is an exploded view of a retractor opening mechanism;

FIGS. 14A, 14B, and 14C are a top plan view of the retractor, a cross-sectional
25 view of the retractor with a push-button clamp assembly attached, and perspective view from above of an L-shaped stationary section of the retractor with a toothed cross bar, respectively;

FIGS. 15A and 15B are a perspective view from above of a retractor with an
30 extension device attached, and a cross-section view of a push-button clamp assembly, respectively;

FIGS. 16A, 16B, and 16C are a perspective view from above of a retractor with an extension device attached, an exploded view of a retractor opening mechanism, and
35 an exploded view of a retractor blade attachment to a retractor frame member, respectively;

- 5 -

FIGS 17A, 17B, and 17C are a cross-sectional view of a cam lock in the open and locked positions, an exploded view of a cam lock, guide pin and retractor frame member, and a perspective view from above of a cam lock clamp assembly, respectively;

FIGS. 18A-1, 18A-2, 18A-3, 18B-1, 18B-2, 18B-3, 18B-4 and 18C are an exploded view from below of a tool shaft, a swivel link assembly, and a U-shaped end effector, a series of schematic illustrations of a swivel link, and a perspective view from above of an assembled swivel link, respectively.

10 Detailed Description of the Illustrated Embodiments

Referring to FIGS. 1-10B, one embodiment of a retractor and surgical tool attachment system according to the invention comprises a retractor 2 for spreading and keeping back the walls of an incision in a patient. In describing this embodiment, we will refer to orthogonal axes x, y, and z shown in FIGS. 2B and 2C. Much of the description of this embodiment will apply to the alternative embodiments presented below.

With reference to FIGS. 1-2C, the retractor includes two frame members 4 and 6, and an opening mechanism 8a. The frame members are opposed, co-extensive and generally elongated. Referring to FIGS. 2A-3B, the opening mechanism includes a connector plate 8, a screw gear 10, and a cover plate 14. The frame members have proximal ends 4a and 6a with a semi-circular edge at their ends having gear teeth therein. The ends are pivotly connected to the connector plate so that the frame members rotate about axes 4b and 6b, respectively. Thus, the frame members move substantially in the x-y plane.

The screw gear extends between the toothed proximal ends of the frame members at an angle of approximately thirty degrees, forming an angled worm gear assembly. The screw gear turns on a guide pin 10a that is connected to the connector plate. A cover plate sits on top of the connector plate and proximal ends of the frame members. The cover plate has a conforming angled screw slot to further guide the screw.

Turning the screw drives the helical worm face against the teeth of both proximal ends of the frame members, causing the frame members to pivot in opposite senses substantially in the x-y plane so the two members draw toward each other, or push apart from each other, depending on the direction of rotation. This angled worm gear has advantages. The angled worm gear allows the gear to be self locking, i.e. the retractor can be opened to a fixed separation and it will maintain that separation. Furthermore, the angle of the worm gear facilitates access to the opening mechanism by the retractor operator while maintaining access to the incision.

- 6 -

The frame members include retractor blades 19 and 21, which extend down, transverse to the x-y plane of the frame members. These blades are placed in an incision when the retractor is in a closed position, i.e. when the frame members are in relative spatial proximity to each other. Upon placement of the retractor blades in an incision, the screw can be screwed down into the worm gear causing the frame members to open outwardly and the retractor blades to exert outward pressure on the walls of the incision 15 and 17, and consequently spread and keep open the incision. The frame members, the retractor blade members and the connector plate are made of a strong metal, e.g. stainless steel or titanium.

The blades are modular, i.e. the blades are removably and replaceably attachable to the retractor. The blades can pivot about a substantially vertical axis, as shown so that they conform to the orientation of the incision, or pivot about a substantially horizontal axis. In the embodiment shown in FIGS. 2A and 2C, the blades are angled back, i.e. they tilt outwardly as they extend down, so the angle between the blade and the frame member in the y-z plane is less than 90 degrees. As the blades spread apart an incision, the pressure provided between the blades and at least a wall portion of the incision has a downward component of force, driving the retractor down against the patient's body, stabilizing the retractor. Furthermore, a blade can include a compliant blade element such as an attachable conforming elastomeric pad that attaches to the blade. Such a compliant blade element evenly distributes pressure over at least a wall portion of the incision, reducing trauma to the patient.

With reference to FIGS. 2B and 4, the retractor of this embodiment also includes a fiber optic light guide 63 optically coupled to a light source. In one embodiment, the light guide is bifurcated with each individual light guide running along light guide mounts. Individual light guide 64a travels along light guide mount 65a to a distal end of the frame member 66f, where it is optically coupled to a light wand 66, which is preferably disposable. The light wand provides light to the surgical field while its disposability facilitates sterilization of the retractor.

The disposable light wand includes a mating attachment 66e, for coupling of the light wand to the light guide, light fibers 66, full soft malleable wire 66b (316L), and dual lumen flexible tubing 66c. The tubing contains the fibers and the wire. The wire allows the tubing to be posed in any position. The end of the tubing opposite the conforming attachment has a full epoxy set at the tip. By posing the tube in an appropriate position the surgeon can illuminate an area of interest in the surgical field.

The retractor includes a suction tube 64 b. This tube also contains full soft malleable wire to allow posing of the tube in any position. The proximal end of the tube is attached to a suction device. The distal end of the tube is posed in selected proximity

- 7 -

to the surgical field. A portion of the tube near the distal end of the tube is attached to the retractor at 34c. The suction tube is used to clear blood and other material, improving visual access to the surgical field.

An extension device 13 is attachable to the frame members. The extension
5 device attaches on top of the frame members. In one embodiment, the extension device includes a clamp assembly 16, and a positioning arm 18. The positioning arm is slideably and lockably attachable to the clamp assembly. The positioning arm has a tool holder 20 at its outboard end, that is, at the end that extends toward the incision. The tool holder includes a selectively locking multi-axis adjustable mounting element 22
10 adapted to grip a tool shaft 24 for positioning a tool 26. In this embodiment, the mounting element is a ball and socket joint. A cap nut with an open center tightens down to clamp the ball in the socket at the desired orientation.

Thus, by adjusting the ball and socket joint, the tool may be positioned anywhere in the surgical field. The tool 26, depicted in FIGS. 2A-2C and 6, comprises a tool shaft
15 24, and an end-effector 28 attached to the distal end of the tool shaft.

With reference to FIGS. 2A-2C and 5, the clamp assembly for the positioning arm is a cam lock, although, in other embodiments the clamp assembly could be a selectively locking second multi-axis adjustable mounting element. The cam lock includes a low cylindrical cam lock body 5, which does not project over the wall of the
20 incision. The clamp assembly attaches to the retractor by a docking means 9 that fits into a docking aperture 9a. In this embodiment, the docking means is an expanding slit cylindrical shaft with a shaft expansion pin 9b positioned inside the slit shaft and the docking aperture is a conforming cylindrical opening. The clamp assembly rotates about the axis 7 of the shaft. The positioning arm 18 slideably and lockably mounts in the
25 cylindrical body by means of a substantially rectangular conforming mounting aperture 18a. A locking lever 11 with a cam end 3 rotates about an axis 7a to drive the expansion pin into the expanding shaft while bearing down against the positioning arm to lock both the clamp assembly in a particular rotational position and the positioning arm in a particular horizontal extension position.

When the locking lever 11 is in the up or open position, the positioning arm is
30 free to move through slot 18a and the clamp assembly is free to rotate about axis 7. In addition, the clamp assembly is capable of both removal and insertion in the docking aperture. However, when the locking lever is in the down or locked position, the cam end is rotated so as to place pressure on the positioning arm locking it in place.
35 Furthermore, the cam end pushes the shaft expanding pin down into the cylindrical shaft 9 expanding the shaft in the conforming cylindrical slot so as to prevent rotation of the clamp assembly or removal of the clamp assembly from the docking aperture. Thus, this

- 8 -

clamp assembly allows the positioning and locking of a tool holder at a fixed distance and angle with a single clamp motion.

With reference to FIGS. 6 and 7, the tool holder includes a selectively locking first multi-axis adjustable mounting element 22. The mounting element is adapted to grip a tool shaft. In this embodiment the mounting element is a ball and socket joint including a base 31, a screw down top 27, and a compressible mounting member 29. The mounting member is a ball with a mounting means adapted for attachment to the proximal end of a tool shaft. The screw down top has a conforming spherical shell portion 35 as an internal surface. The compressible ball has grooves 33 that divide the ball body into a plurality of deformable gripping contacts which allow for compression of the ball around the tool shaft 26. The base of the tool holder has a longitudinal slot 37 that allows selective removal and installation of the tool 26, the slot being at least the width of the tool. Thus, a tool slideably attached to the ball can be placed with an essentially horizontal motion into the base of the tool holder through the slot.

Subsequently, the screw down top is placed over the tool shaft and slid down onto the base of the tool holder. By screwing the screw down top down onto the base of the tool holder the conforming spherical shell applies pressure to the ball closing or compressing the grooves and, consequently, locking the ball and tool shaft in rotational and linear position, respectively.

20

EXAMPLE 1

As state above, in this embodiment of a tool according to the invention, the tool 26, depicted in FIGS. 2A-2C, 6, and 8A-10B comprises a tool shaft 24, and a end-effector 28 attached to the distal end of the tool shaft. The tool shaft includes an outer shaft 24b and an inner shaft 24c. Both shafts are hollow. The outer diameter of the inner shaft is substantially similar to the inner diameter of the outer shaft, so that they fit closely, while the inner shaft and the outer shaft are capable of motion relative to each other. The outer shaft has longitudinal slits 24a which allow the outer shaft wall to be compressed against the inner shaft.

The outer shaft has a pivot extension 30 on a distal end. The inner shaft has a pivot pin 39 and an inner shaft pivot aperture 40. The end-effector has a pivot link 42. The end-effector is pivotly attached to both the inner and outer shafts at the pivot pin and pivot extension, respectively. The pivot aperture of the inner shaft allows the pivot pin to both rotate and move transverse to the longitudinal axis of the tool shaft and transverse to the axis of the pivot pin. Movement of one shaft relative to the other thus causes articulation of the end-effector about an axis substantially parallel to the axis of

the pivot pin. Furthermore, when the mounting element described above, e.g. the compressible ball 29, grips the tool shaft, the wall of the outer shaft is squeezed against the inner shaft, fixing the articulation angle of the end-effector. Thus, in one act of locking the mounting element, the tool is universally positioned and the articulation of the end-effector is fixed. In a similar manner, the tool can be configured so that relative motion of two tool shaft elements can provide rotation of an end-effector about an axis that is parallel to the tool shaft.

With reference to FIG. 9A-5, the illustrated end-effector 28 includes suction channels 34 channel milled into its bottom or contact side to clear the surgical field of blood and other material. Suction channel openings 36 are located on the sides of the end-effector. With reference to FIG. 6, a suction and blower tubeset 24d passes down the inside of the inner tool shaft and the blower passes out the distal end of the tool shaft. With reference to FIG. 2A, the suction tube attaches to the end-effector to provide suction to the suction channels milled into the end-effector. Thus, in one embodiment, the end-effector is a U-shaped device with two prongs. Each prong includes a suction channel used to clear the surgical site of blood and other material.

With reference to FIGS. 6 and 9A-7, the cross section profile of the end-effector is an open profile. In other words, the profile of the end-effector provides the surgeon with enhanced access to the tissue located between the prongs. In one embodiment the distance between the prongs is at least about 8 to 15 mm. In another embodiment, the open profile includes a tapered cross section profile when viewed in a plane perpendicular to the prongs, such that the vertical height of the prongs decreases with proximity to the surgical site.

In another embodiment, the contact surfaces of the end-effector, that is the surfaces of the end-effector that make contact with the surgical site, are textured. The contact surfaces are textured so as to prevent slipping and minimize movement of tissue at the surgical site relative to the end-effector.

With reference to FIGS. 9B and 9C, according to one embodiment of the invention, wire 39 with burrs 41 on its surface is imbedded in the underside of an end-effector, such that a predetermined segment of the wire is exposed on the contact surface of the end-effector. The burrs dig into tissue such that placement of the end-effector in contact with tissue allows the end effector to provide lateral or pull up tension on the tissue. Further, it allows the end effector to maintain contact with the tissue. The wire can be silver soldered into place.

With reference to FIG. 10A and 10B, other embodiments include different end-effectors 38, 38a, 38b, 38c, and 38d. One example of a different end-effector is a quick connect vessel occluder for stabilizing or occluding a vessel. Such a device can be used

- 10 -

in the present invention for pinching a vessel without piercing the tissue of the heart. Other end-effectors include a hemostat, a fork, a rake to act as a retractor, a needle driver, forceps, scissors, and clip appliers. With reference to FIG. 10B, an end-effector can include an articulating camera 38e.

- 5 In another embodiment, the end-effector includes at least one clamp for the attachment of the ends of a vessel occlusion band. In order to occlude a vessel, surgeons often use a type of rubber band. A surgeon passes the band around the vessel, perhaps more than once, and then tightens the band, pinching the vessel without piercing the vessel or neighboring tissue. Commonly, a surgeon will then pull the ends of the band
10 out of the incision and tie them down. In this embodiment, the end-effector includes a clamp so that a surgeon may tie the ends of a vessel occlusion band to the end-effector maintaining greater access to the surgical field.

EXAMPLE 2

- 15 Referring to FIGS. 11A-13, another embodiment of a retractor and surgical tool attachment system according to the invention comprises a retractor 102 for spreading and keeping back the walls of an incision in the patient. The retractor includes first and second retractor frame members 104 and 106. The second frame member 106 similar in
20 configuration to the first frame member, has a toothed proximal end 157. The toothed proximal end of frame member 106 sits on the proximal end 159 of the first retractor frame member. An opening mechanism 150, sits on the proximal ends of the frame members and comprises a cover plate 155 and a series of gears 151. The gears fit into slot 143 in the second retractor frame member and a further slot 141 in the first retractor
25 frame member. The retractor frame members pivot around a shaft 161 extending down from the cover plate. The cylindrical shaft inserts in slots 163 and 165 of second retractor frame and first retractor frame, respectively. The opening mechanism and gears comprise an overhead gear assembly with a ratchet system to maintain the retractor in a set position. The cover plate comprises a crank handle 152, a ratchet switch 154, and a
30 ratchet lock pin 156. Depending on the setting of the ratchet switch the retractor can be alternatively opened and closed by turning the crank handle, rotating the gear assembly, and rotating the second retractor frame member.

- Attached to the retractor frame members are modular retractor blades 119 and 121. With reference to FIG. 16C, the modular retractor blade is connected to retractor
35 frame member by placement of the retractor blade in the retractor frame member slot 379. Insertion of the retractor screw 380 into a retractor blade cylindrical slot 391 secures the retractor blade to the retractor frame member.

- 11 -

The retractor blades can be deflectable. With reference to Fig 12C, the retractor blade can pivot about a pivot point 168, so that the blades can fit flush to the walls of an incision.

- The blades can be soft so as to apply pressure evenly on the walls of an incision.
- 5 By applying even pressure on the walls of the incision, soft retractor blades reduce surgical trauma. According to one embodiment of the invention, the retractor blade can comprise a disposable elastomeric cushion attachment 162.

- With reference to FIGS. 11A-13, the retractor may also incorporate a fiber optic light assembly 195, the fiber optic light assembly comprises a light source 193 and at least one optic fiber 164. The optic fiber runs along the side of the retractor frame member opposite the incision to the distal end of the retractor frame member, down below the retractor blade, and out the fiber optic exit 160. The output end of the optic fiber located at fiber optic exit 160 emits light so as to illuminate the inside of the body cavity.
- 10

- 15 With reference to FIGS. 12A and 12B, the clamp assembly is a cam lever clamp assembly 116. A cam lever clamp assembly is spring loaded such that pushing down on the locking lever 111 locks the clamp assembly in rotational position and the positioning arm in linear position. By subsequently pushing on the locking lever 111, the clamp assembly is released allowing freedom of rotation of the clamp assembly and linear motion of the positioning arm.
- 20

- The spring loaded clamp assembly achieves its functionality in the following way. The clamp assembly comprises spring 160, pin 161, and grooves 163. When the locking lever is in the up and open position, the pin is pulled out of the grooves so as to allow rotation of the clamp assembly. Furthermore, when the locking lever 111 is in the up and open position, the cam end 103 does not apply pressure to the positioning arm 118 allowing linear motion of the positioning arm. However, when the locking lever is in the down and closed position the pin is inserted in the grooves preventing rotation or motion of the clamp assembly. Further, the cam end 103 places pressure on the positioning arm preventing linear motion of positioning arm.
- 25

- 30 With reference to FIG. 12A, according to one embodiment of this invention, conforming cylindrical slots 109a are provided on the retractor frame members to allow alternative positioning of the extension device. By placing the extension device in the appropriate conforming cylindrical slot, a surgeon is able to position the extension device, and consequently the surgical tool, in an appropriate location while minimizing obstruction caused by the extension device and tool.
- 35

EXAMPLE 3

- 12 -

With reference to FIGS. 14A-15B, an embodiment of the retractor and surgical tool attachment system according to the invention comprises a retractor 202. The retractor includes a substantially L-shaped stationary section 208 which has a stationary frame member 204 and a moveable frame member 206. The moveable frame member, similar in configuration to the stationary frame member, has a toothed cross bar or rack 210 attached to it. The stationary frame member has a housing 212, which slides on the rack. The substantially L-shaped stationary section also includes an opening mechanism crank lever 252. Rotating the crank lever rotates a gear in the toothed cross bar of the moveable frame member alternatively moving the moveable frame member in or out.

Both frame members include universal mounting grooves 270. These mounting grooves allow an extension device 213 to be slideably positioned along the frame member within the groove.

The extension device includes a push-button clamp assembly 216. The push-button clamp assembly includes a push-button 274, a spring 160 and ball bearings 276. The push-button clamp assembly functions in the following way. When the push-button is pushed the positioning arm is released and the ball bearings loosen. When the ball bearings loosen the clamp assembly is free to rotate. However, upon pushing the push-button again the positioning arm is captured and the clamp assembly is locked in rotational position.

EXAMPLE 4

Referring to FIGS. 16A - 17B, another embodiment of a retractor and surgical tool attachment system according to the invention comprises a retractor 302. The retractor incorporates the general shape of Example 2 with the universal mounting groove of Example 3. The opening mechanism comprises a foldaway crank lever 352 a gear 357 attached to the crank lever, and, a cover plate 355. The retractor comprises a first retractor frame member 304 and a second retractor frame member 306. The proximal end of the second retractor frame member sits on top of the proximal end of the first retractor frame member. The opening mechanism sits on the proximal ends of the frame members. The proximal end of the second retractor frame member has a slot 393 with ratchet teeth 392. The gear of the opening mechanism fits in the slot of the second frame member. By turning the crank lever which is attached to the opening mechanism gear, the gear rotates against the ratchet teeth of the slot of the proximal end of the second frame member, causing the second frame member to rotate about the axis.

- 13 -

397. The rotation of the second retractor frame member causes the retractor to open and spread apart an incision.

This embodiment incorporates a fiber optic routing assembly 379. The fiber optic routing assembly comprises an opening mechanism sheath 379a, optical fiber 364, and fiber optic light balls 377. One end of the optical fiber is connected to a light source. Light travels down the optical fiber, from the light source, into the opening mechanism sheath, and to the light balls, illuminating the surgical field. Further, another optical fiber 366, is mounted in a fiber optic track 398 located on the outside of a retractor frame member. The optical fiber extends down below a retractor frame member and out to a retractor blade 319 or 321, through the fiber optic exit 360. Again, light from a light source travels along the optical fiber and is emitted at the fiber optic exit, further illuminating the surgical field.

With reference to FIGS. 2A and 16A, this embodiment also incorporates the ability to apply suction to the surgical field to remove blood and other material. The suction assembly comprises suction tubing 333 attached at one end to a suction pump and at the other end to an end-effector via tubing attachments 28a. The suction tubing could pass down the center of a tool shaft or down along side a tool shaft.

Another embodiment incorporates the ability to blow on the surgical field. A blower comprises blower tubing similar to the suction tubing. The tubing is a fully soft, unannealed material with a wire backbone to allow positioning.

Referring to Figures 16A, and 17A - 17C, the extension device includes a cam lock clamp assembly 316. The cam lock clamp assembly includes a cam lock 301 and a guide pin 380. The head of the guide pin fits into the cam lock guide pin slot 301b. The positioning arm slides through the cam lock and guide pin positioning arm slots, 301a and 380a, respectively. The guide pin is inserted in the universal mounting groove aperture 370a, such that the edges of the universal mounting groove slide in the universal mounting groove slot of the guide pin. Thus, the guide pin and cam lock clamp assembly can be located anywhere in the universal mounting groove. The cam lock can be rotated and the positioning arm can move linearly when the locking lever 311 is in the up and open position.

Upon lowering the locking lever to the down position the cam lock clamp assembly is locked. The locking lever rotates the cam lock about an axis that is substantially parallel to axis 318a. The end of the cam lock is aspherical such that pushing the locking lever to the closed position forces the bulbous end of the cam lock down against the retractor frame member. Because of the interaction of the positioning arm, cam lock, and guide pin, the guide pin bottom 380c is forced up against the universal mounting groove surface. The pressure between the guide pin bottom and the

- 14 -

universal mounting groove surface prevents the cam lock clamp assembly from rotating. Furthermore, the pressure between the cam lock and the positioning arm, and the guide pin and the positioning arm prevents the positioning arm from moving linearly.

5

EXAMPLE 5

Referring to FIGS. 9A-2, and 18A-1 - 18C, another embodiment of an end-effector tool shaft attachment is illustrated comprising a swivel link 482. The swivel link comprises cylindrical swivel link rods 482a which attach to conforming slots 427a and 427b in first and second tool shaft section 426a and 426b, respectively. The swivel link has an end-effector attachment 482b that connects to a conforming end-effector slot 28a. Thus, relative motion of the first and second tool shaft section causes a rotation of the swivel link about an axis 499. This rotation of the swivel link causes rotation of the end-effector.

15 The above embodiments according to the invention have several advantages. Heart stabilization assemblies which attach to a retractor are superior to hand held devices because an assistant's hands are not in the way and because they are more effective in limiting the motion of the heart. A surgeon can rapidly place a surgical tool using this invention. Furthermore, this embodiment allows the surgeon to rapidly
20 remove the tool, restoring access to the surgical arena.

This invention allows easier and more complete access to the surgical field defined by the retractor because the position of the surgical tool is completely independent of the retractor. This position independence is useful. As described above, when a heart surgeon opens a surgical cavity and places a retractor, the patient's heart is covered with an opaque tissue. Unable to clearly determine the location of the artery,
25 the surgeon must approximate the location of the artery and place the retractor accordingly. Upon removing the opaque tissue and discovering that the artery is not located near the center of the retractor, it be necessary to adjust the position of the end-effector. Because the position of the tool is completely independent of the retractor, the
30 surgeon merely adjusts the tool over the artery of interest. The ability to adjust the location of the tool without adjusting the position of the retractor will reduce the time, cost, and trauma of surgery.

Further, the surgeon is free to determine the insertion point and the insertion angle of the tool. This freedom is important because it allows the surgeon to place the
35 tool near the edge of the incision and at an appropriate angle so as to provide the surgeon with greater access to the surgical field. Thus, this invention provides a surgeon with

- 15 -

flexibility. This invention can be used in many operations including LAD coronary artery operations and valve replacement operations.

Importantly, this invention improves minimally invasive direct surgery. The invention allows a surgeon to place a tool effectively anywhere in the surgical field, articulate the end-effector, and freeze the position of the tool and the articulation of the end-effector in one act, the locking of the mounting element.

Because many varying and different embodiments may be made within the scope of the inventive concept herein taught, and because many modifications may be made in the embodiments herein detailed in accordance with the descriptive requirement of the law, it is to be understood that the details herein are to be interpreted as illustrative and not in a limiting sense.

- 16 -

What is claimed is:

1. Surgical apparatus comprising
a retractor for spreading open an incision in a patient, and
5 at least one extension device secured on the retractor,
the extension device having a tool holder at an outboard end
thereof, the extension device extending the tool holder toward the incision,
the tool holder including a selectively locking first multi-axis
adjustable mounting element adapted to grip a tool shaft for positioning a tool over a
10 range of positions,
the first mounting element enabling the tool to be
selectively positioned relative to the tool holder in a surgical field by positioning the
tool, and locking the mounting element of the tool holder.
- 15 2. Apparatus according to claim 1, wherein the first mounting element includes a
ball and socket joint.
3. Apparatus according to claim 1, wherein the tool holder of the extension device
further including
20 means forming a slot for allowing selective removal and installation of
the tool, the slot being a longitudinal opening responsive to the width of the tool.
4. Apparatus according to claim 1, wherein the retractor comprises
generally opposed retractor blades for insertion into the incision and for
25 applying pressure on at least a wall portion of the incision,
the retractor blades being removably and replaceably attachable to the
retractor.
5. Apparatus according to claim 1, wherein the retractor comprises
30 generally opposed retractor blades for insertion into the incision and for
applying pressure on at least a wall portion of the incision,
each retractor blade having deflectable means for allowing that retractor
blade to be contiguous with at least a wall portion of the incision.
- 35 6. Apparatus according to claim 1, wherein the retractor comprises
a fiber optic light assembly including

- 17 -

a fiber optic light guide for illuminating the surgical field, the light guide having a first end optically coupled to a light source and a second end mountingly connected to the retractor, and

5 a disposable light wand optically coupled to the second end of the fiber optic light guide.

7. Apparatus according to claim 1, wherein the retractor comprises generally opposed retractor blades for insertion into the incision and for applying pressure on at least a wall portion of the incision,
10 at least one retractor blade including a compliant retractor blade element.

8. Apparatus according to claim 1, wherein the retractor further comprises at least one suction tube having the proximal end of the tube connected to a suction device and the distal end of the tube posed in selected proximity to the surgical site, a portion of the
15 tube near the distal end of the tube being attached to the retractor.

9. Apparatus according to claim 1, wherein the extension device comprises a clamp assembly secured on the retractor, and a positioning arm extending from the clamp assembly, the positioning
20 arm supporting the tool holder at an outboard end thereof for disposing the mounting element to enable the tool holder to position the tool selectively in a surgical field by the operations of positioning the positioning arm relative to the retractor, securing the positioning arm, positioning the tool in the tool holder, and locking the first mounting element of the tool holder.

25 10. Apparatus according to claim 9, wherein the retractor includes at least one docking aperture and the clamp assembly includes a docking means structured for insertion in and removal from the docking aperture located on the retractor.

30 11. Apparatus according to claim 9, wherein the retractor comprises opposed and substantially co-extensive generally elongated frame members, and the positioning arm being slidably and lockably connected to the clamp assembly.

35 12. Apparatus according to claim 11, wherein the retractor comprises

- 18 -

generally opposed retractor blades for insertion into the incision and for applying pressure on at least a wall portion of the incision,

at least one retractor blade having an angle between the frame member and the retractor blade less than 90 degrees.

5

13. Apparatus according to claim 9, wherein the clamp assembly comprises a second multi-axis adjustable mounting element.

14. A surgical tool comprising

10

a tool shaft having a longitudinal axis,
an end-effector attached to a distal end of the tool shaft, and
a compressible mounting member attached to a proximal end of the tool shaft.

15

15. Apparatus according to claim 14, wherein the mounting member is a ball with a mounting means adapted to grip the tool shaft.

16. Apparatus according to claim 14, wherein the compressible mounting member is slidable along the tool shaft.

20

17. Apparatus according to claim 14, wherein the end-effector is rotatable about a rotation axis extending transverse to the axis of the tool shaft.

18. Apparatus according to claim 14, wherein the tool further comprises

25

a first tool shaft element,
a second tool shaft element, and
an end-effector link element pivotally attached to the first and second tool shaft elements, the tool shaft elements having longitudinal axes substantially parallel to the axis of the tool shaft, and the tool shaft elements being capable of relative motion substantially in the direction of the axis of the tool shaft, the relative motion causing articulation of the end-effector link element about an axis extending transverse to the axis of the tool shaft.

30

19. Apparatus according to claim 18, wherein the first and second tool shaft elements comprise generally opposed front and back tool shaft elements, respectively, and the end-effector link element comprises a swivel link coupled to the front and back tool shaft elements and connected to the end-effector.

35

20. Apparatus according to claim 18, wherein the first and second tool shaft elements comprise co-axial inner and outer shafts, respectively, the inner shaft slidably disposed within the outer shaft, the outer shaft being hollow and having longitudinal slits, and the
5 outer diameter of the inner shaft being substantially similar to the inner diameter of the outer shaft.

21. Apparatus according to claim 20, wherein
the outer tool shaft has a pivot extension on a distal end thereof,
10 the inner shaft comprises
a pivot pin, having a longitudinal axis, attached to a distal end of the inner shaft and extending transverse to the axis of the tool shaft, and
a means forming a pivot aperture adapted to contain the pivot pin, adapted to allow the pin to rotate, and adapted to allow the pin to move transverse to the
15 axis of the tool shaft and transverse to the axis of the pivot pin, and
the end-effector link element comprises a pivot link adapted for pivotly attaching to the pivot extension and the pivot pin,
such that movement of the inner shaft relative to the outer shaft causes articulation of the end-effector about an axis substantially parallel to the axis of the pivot
20 pin.

22. Apparatus according to claim 18, wherein
the inner shaft includes a means forming a hollow longitudinal passage,
and
25 the surgical tool further comprises at least one suction tube having one end of the tube connected to the tool in selected proximity to the distal end of the tool shaft and the other end of the tube extending away from the surgical field, at least a portion of the tube passing through the hollow longitudinal passage of the inner shaft.

30 23. Apparatus according to claim 18, wherein
the inner shaft includes a means forming a hollow longitudinal passage,
and
the surgical tool further comprises at least one blower tube connected in selected proximity to the distal end of the tool shaft and the other end extending away
35 from the surgical field, at least a portion of the blower tube passing through the hollow longitudinal passage of the inner shaft.

24. Apparatus according to claim 14, wherein the tool has means forming a hollow passage in the tool shaft, aligned substantially parallel to the longitudinal axis of the tool shaft, the hollow passage adapted for containing at least one tube.
- 5 25. Apparatus according to claim 14, wherein the end-effector further comprises an end-effector element with a textured surface.
26. Apparatus according to claim 14, wherein the end-effector further comprises an end-effector element with a microtraumatic surface adapted to engage tissue.
- 10 27. Apparatus according to claim 14 wherein the end-effector includes a generally U-shaped member,
the U-shaped member having at least two prongs.
- 15 28. Apparatus according to claim 27, wherein the end-effector comprises contact elements forming contact surfaces for making contact with the surgical site,
the contact elements of the end-effector having a separation spacing of at least about 8 to about 15 mm apart.
- 20 29. Apparatus according to claim 27, wherein the prongs of the U-shaped end-effector element have a tapered cross section profile when viewed in a plane perpendicular to the prongs, such that the vertical height of the prongs decreases with proximity to the surgical site.
- 25 30. Apparatus according to claim 14, wherein the end-effector is selected from the group of instruments including hemostats, forks, rakes, needle drivers, forceps, scissors, cameras, and clip appliers.
31. Apparatus according to claim 14, wherein the end-effector further comprises at
30 least one clamp for the attachment of the ends of a vessel occlusion band.
32. Apparatus according to claim 14, wherein the end-effector is attached to the tool shaft by a selectively locking third multi-axis adjustable mounting element.
- 35 33. Apparatus according to claim 14, wherein the mounting member attached to a proximal end of the tool shaft is a knurled, elastomeric ball with a mounting means adapted to grip the tool shaft.

- 21 -

34. Apparatus according to claim 14, wherein the end-effector is rotatable about a rotation axis extending substantially parallel to the axis of the tool shaft.

- 5 35. A surgical apparatus comprising
an extension device, the extension device including
a clamp assembly for adjustably locking to a support frame, and
a positioning arm movably positioned in the clamp assembly,
the positioning arm having a tool holder at an outboard
10 end thereof,
the tool holder including a ball - socket joint adapted to
position and secure a tool shaft extending through the ball - socket joint for locking
articulation,
whereby a variety of tools having a tool shaft each with an end-effector
15 are reliably positioned in an operating arena below the frame.

36. Surgical apparatus comprising
a retractor for spreading open an incision in a patient, and
at least one extension device secured on the retractor,
20 the extension device having a tool holder at an outboard end
thereof, the extension device extending the tool holder toward the incision,
the tool holder including a selectively locking ball and socket
joint, and
a tool comprising
25 a tool shaft adapted for gripping by the ball and socket joint, the
tool shaft having
a first shaft element,
a second shaft element,
and an end-effector rotatably attached to a distal end of the tool shaft such that
30 relative motion of the shaft elements causes articulation of the end-effector and such that
locking of the ball and socket joint squeezes the tool shaft, limiting the relative motion
of the tool shaft elements and fixing the articulation of the end-effector,
the ball and socket joint enabling the tool to be selectively positioned relative to
the tool holder in a surgical field and enabling the end-effector to be placed in fixed
35 articulation by positioning the tool, rotating the end-effector, and locking the ball and
socket joint of the tool holder.

- 22 -

37. A retractor with an angled worm gear opening mechanism comprising
a connector plate,
at least two frame members with ratcheted proximal ends rotationally
connected to the connector plate, and
5 a screw adapted for screwing between the ratcheted proximal ends of the
frame members, the axis of the screw being out of the plane of movement of the frame
members such that turning of the screw causes the screw to travel between the ratcheted
proximal ends of the frame members, in turn, causing at least one of the frame members
to rotate.
- 10 38. A surgical method comprising the steps of
retracting walls of an incision with a retractor to allow access to a surgical
field,
lockably attaching an extension device to the retractor, the extension
15 device having a tool holder at an outboard end thereof, the tool holder holding a tool by
means of a selectively locking first multi-axis adjustable mounting element, the
extension device extending from the retractor to position the tool holder adjacent the
incision and extending from the retractor,
positioning a tool comprising a tool shaft and an end-effector attached to
20 a distal end of the tool shaft, such that the tool shaft extends in selected proximity to the
perimeter of the surgical field, and the end-effector is in contact with tissue, and
securing the tool in the first mounting element of the tool holder, thereby
fixing the tool in the surgical field.
- 25 39. The method according to claim 38, wherein the step of positioning the tool with
its end-effector in contact with tissue further comprises the step of positioning the end-
effector so as to push down in a region about a cardiac artery locally limiting the motion
of the heart.
- 30 40. The method according to claim 38, wherein the step of positioning the tool
further comprises the step of positioning the end-effector in contact with tissue so as to
pull up on the tissue, the end-effector having at least one microtraumatic surface.
- 35 41. The method according to claim 38, wherein the step of positioning the tool
further comprises the step of positioning the end-effector in contact with tissue so as to
provide a lateral force on the tissue, the end-effector having at least one microtraumatic
surface.

1/20

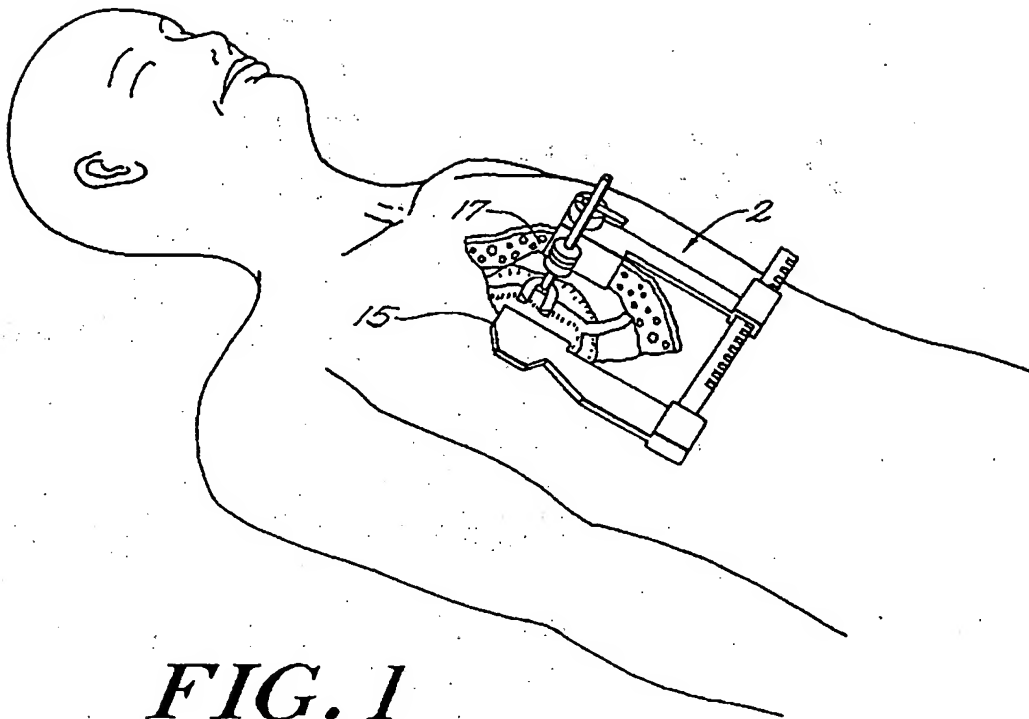


FIG. 1

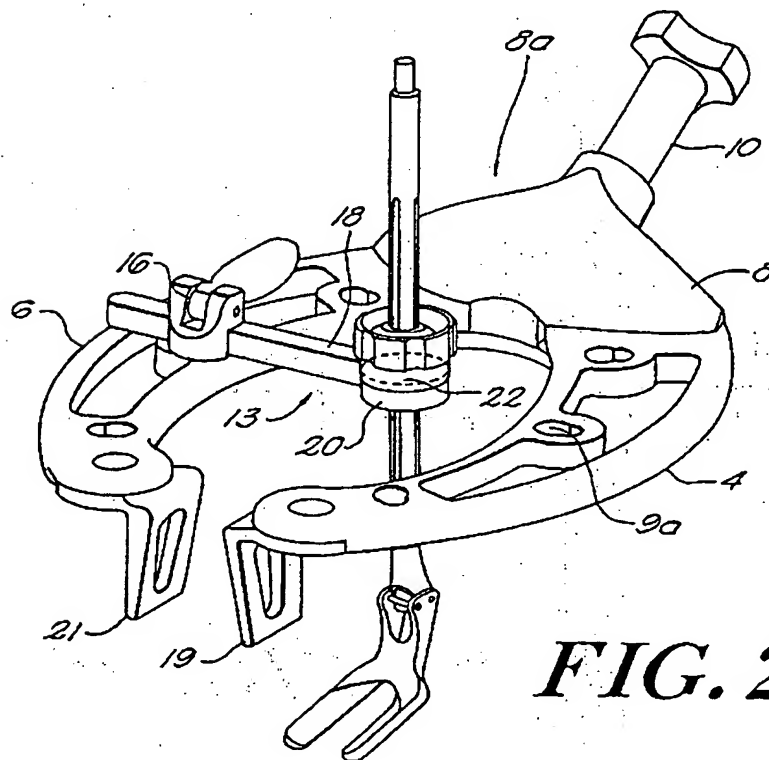


FIG. 2A

2/20

FIG. 2B

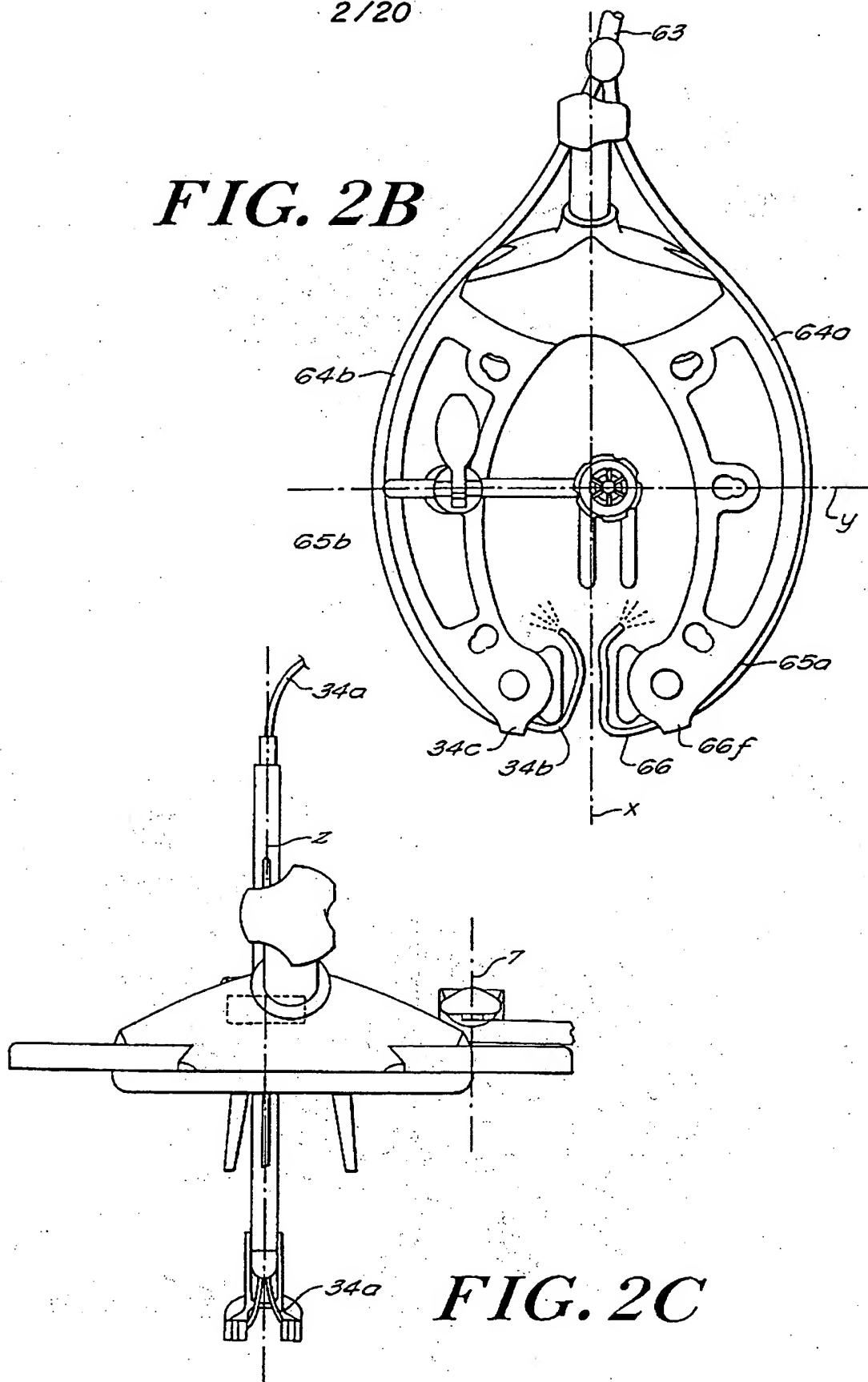


FIG. 2C

3/20

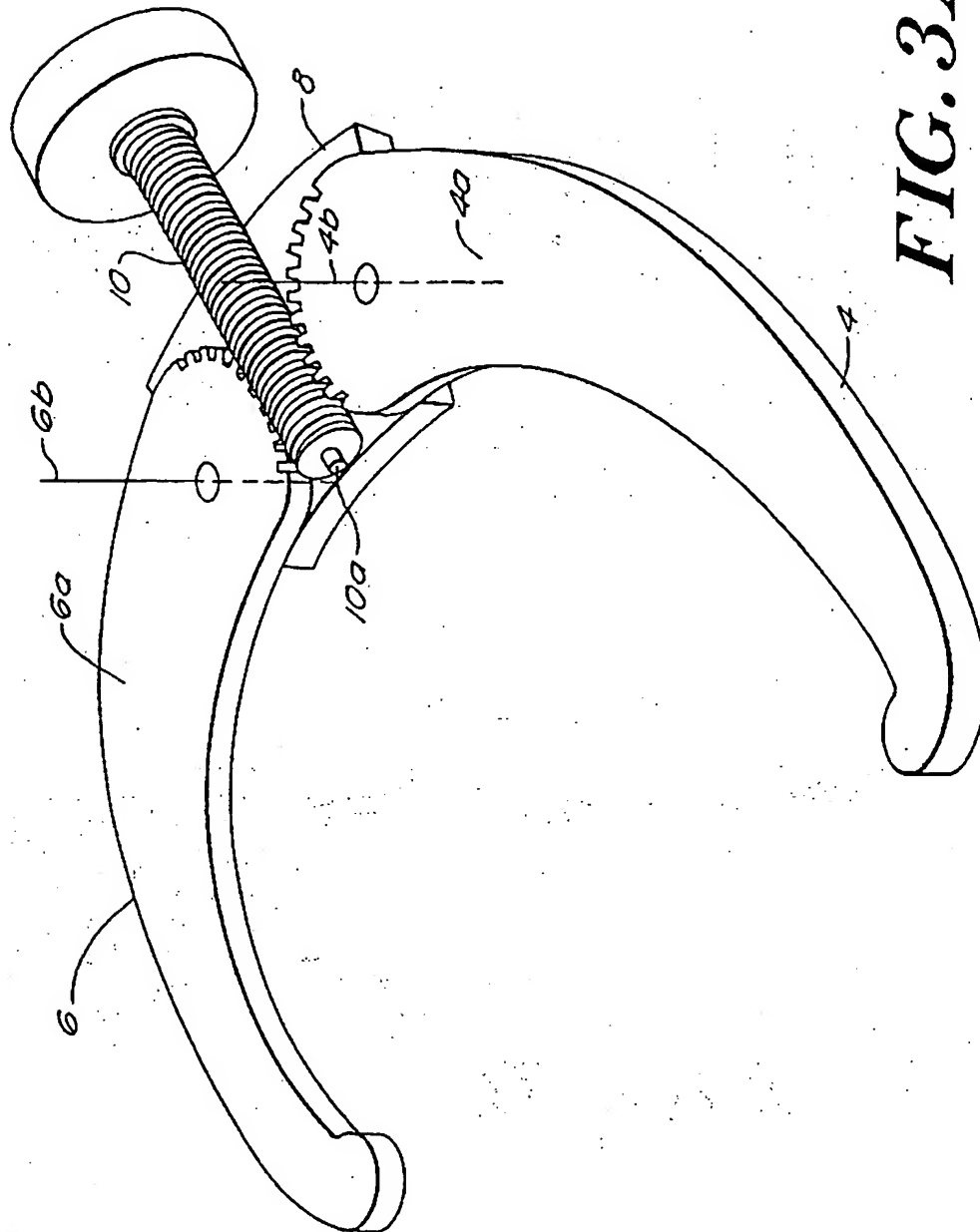
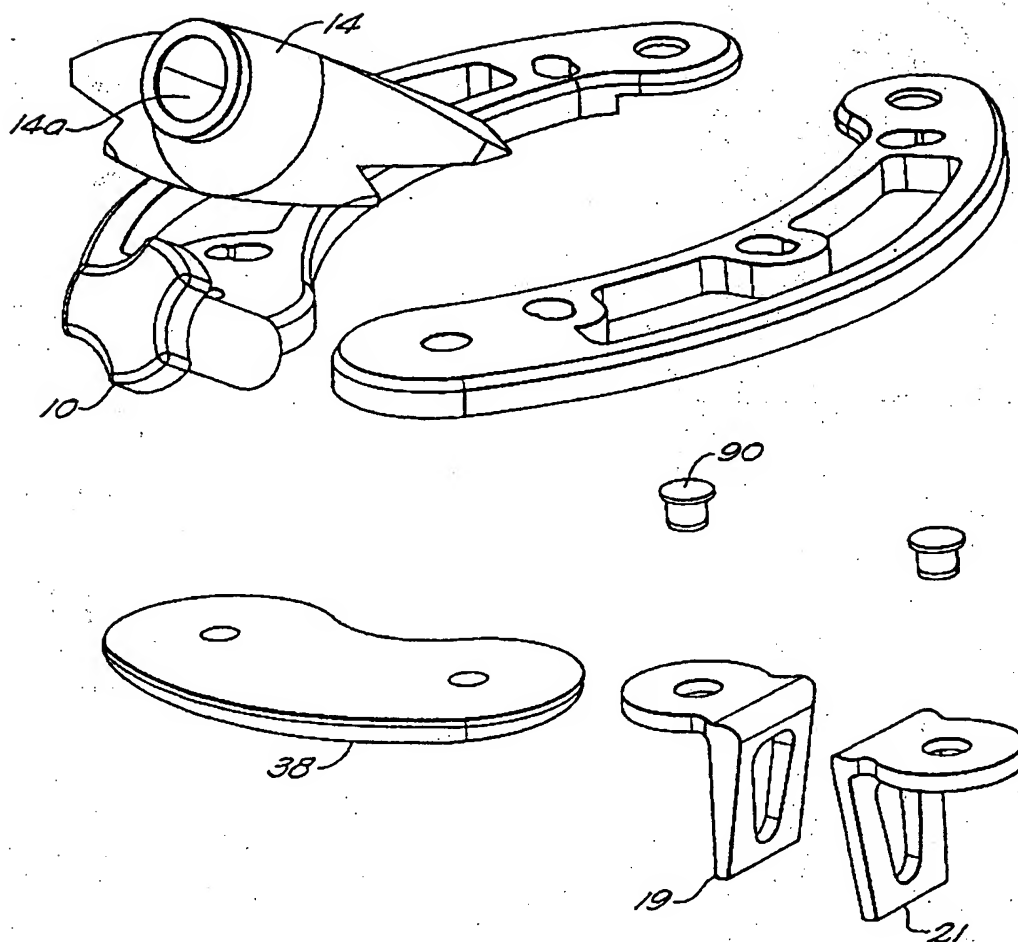


FIG. 3A

4/20

**FIG. 3B**

5/20

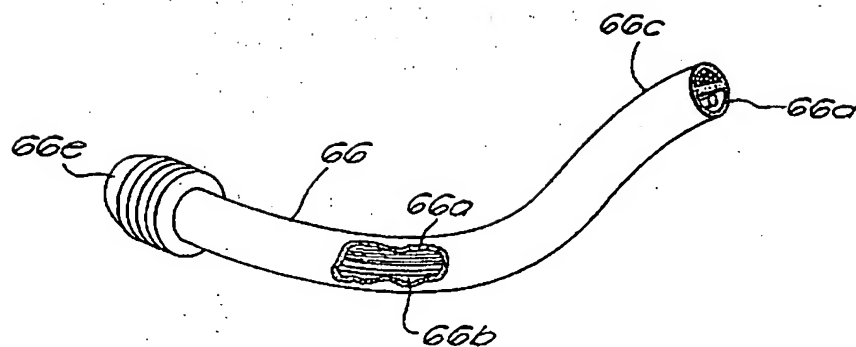


FIG. 4

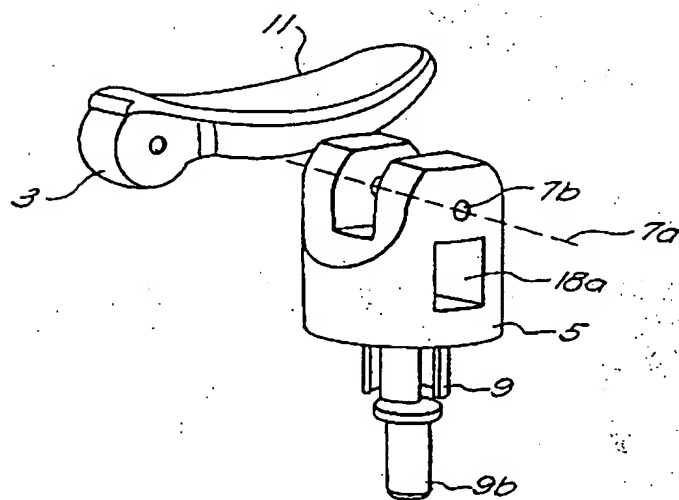


FIG. 5

SUBSTITUTE SHEET (RULE 26)

FIG. 6

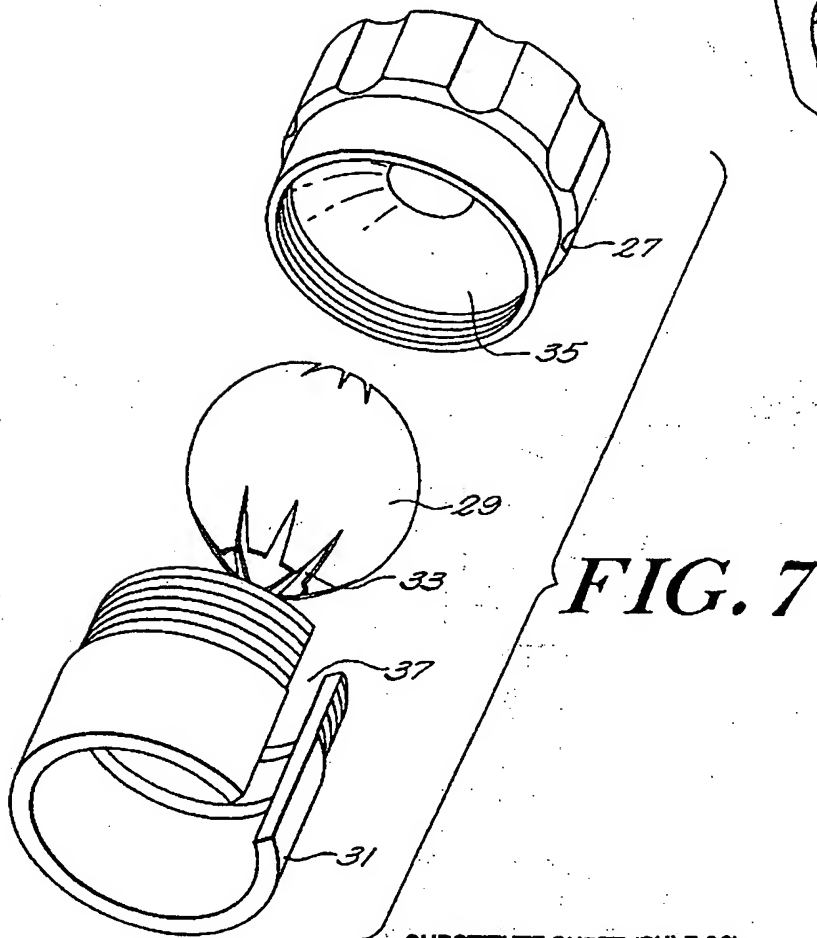
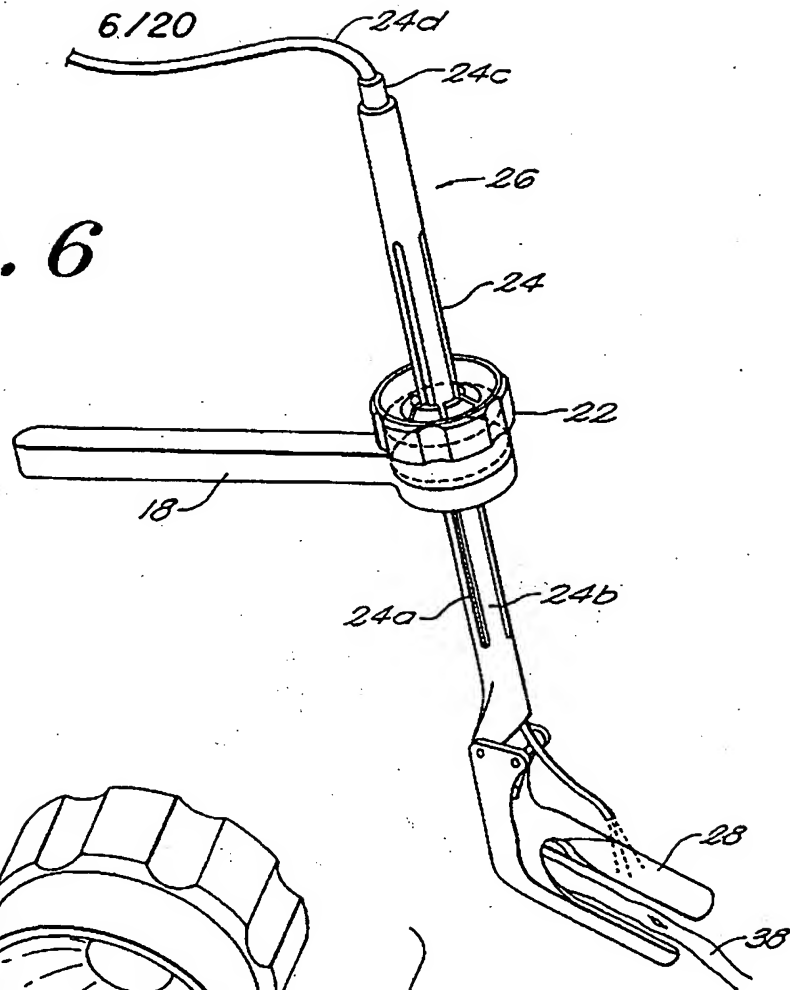


FIG. 7

7/20

FIG. 8A

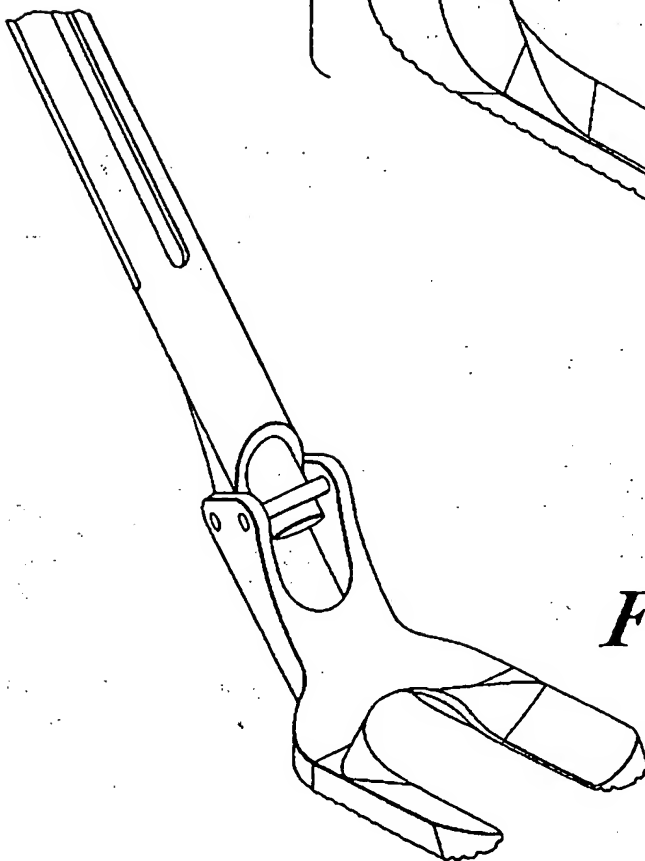
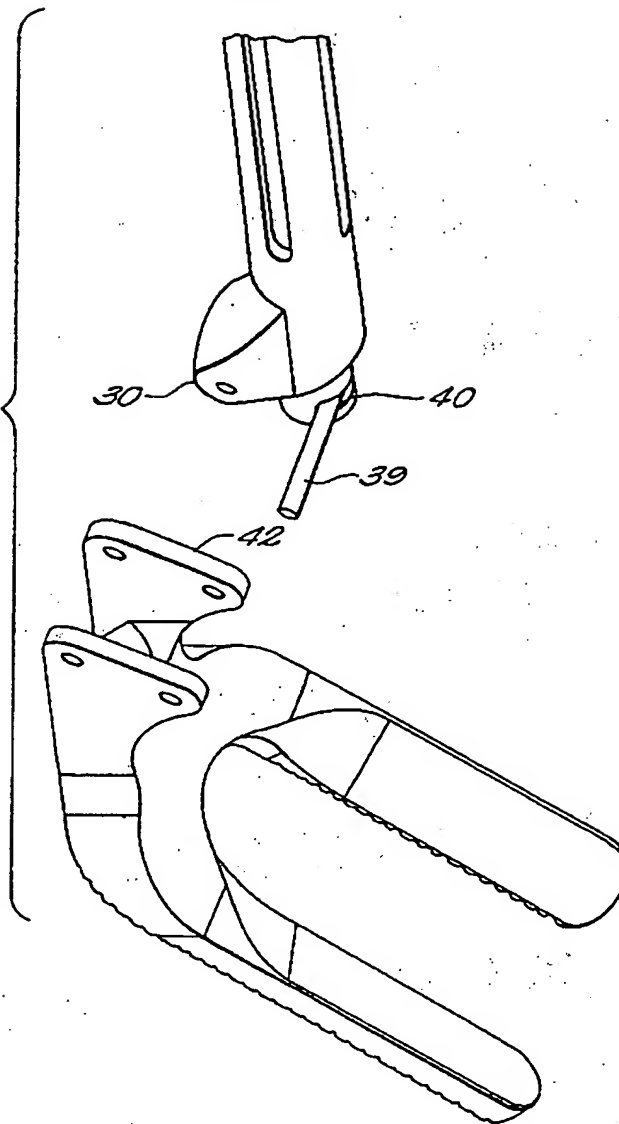


FIG. 8B

8/20

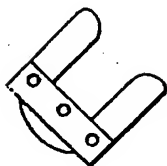
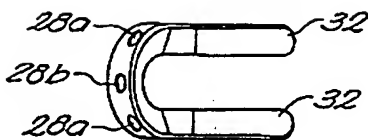


FIG. 9A-2

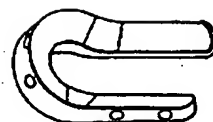


FIG. 9A-3



FIG. 9A-4

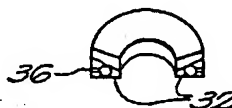


FIG. 9A-5

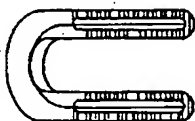


FIG. 9A-7

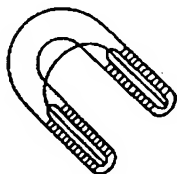


FIG. 9A-6

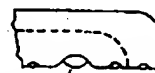


FIG. 9A-8

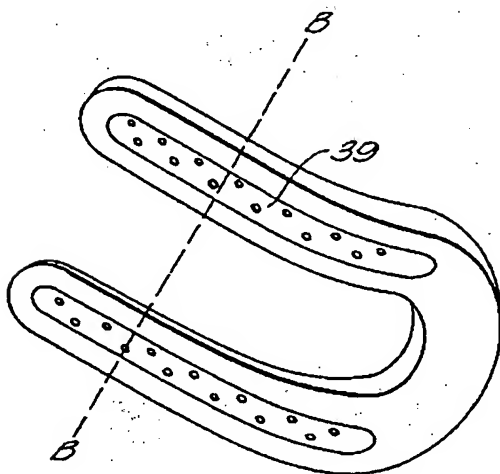


FIG. 9B

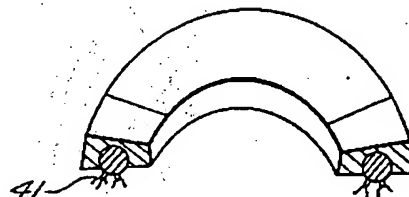


FIG. 9C

9/20

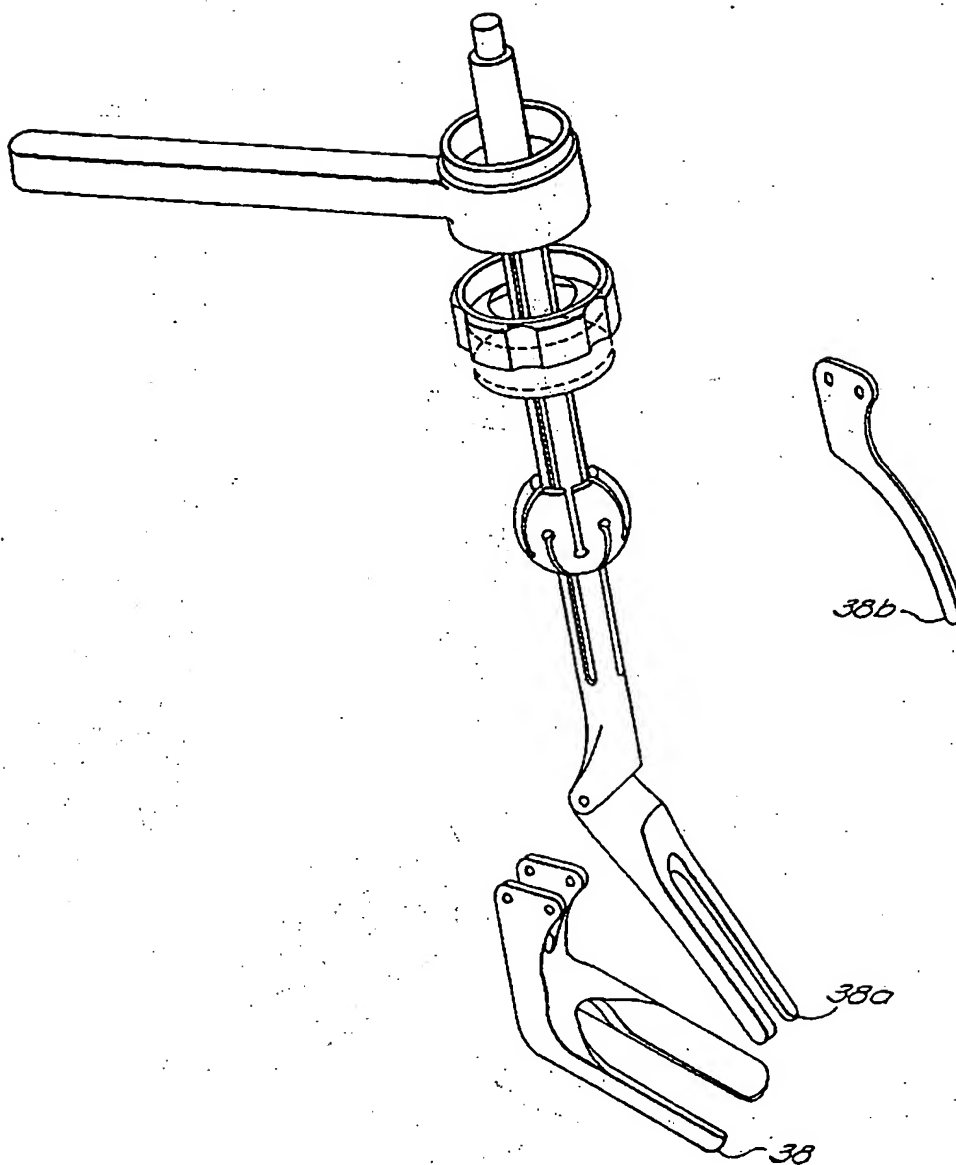


FIG. 10A

SUBSTITUTE SHEET (RULE 26)

10/20

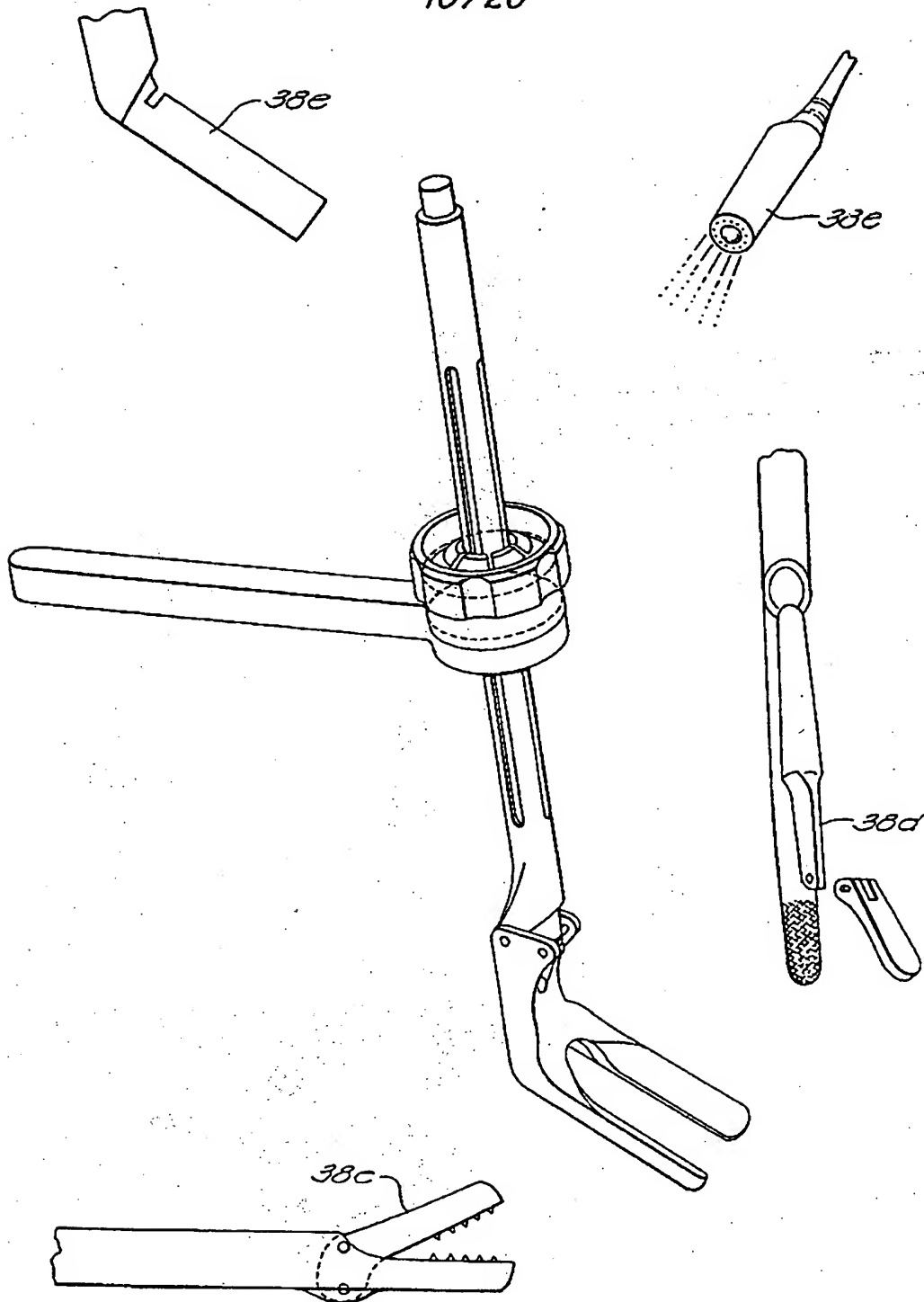


FIG. 10B

SUBSTITUTE SHEET (RULE 26)

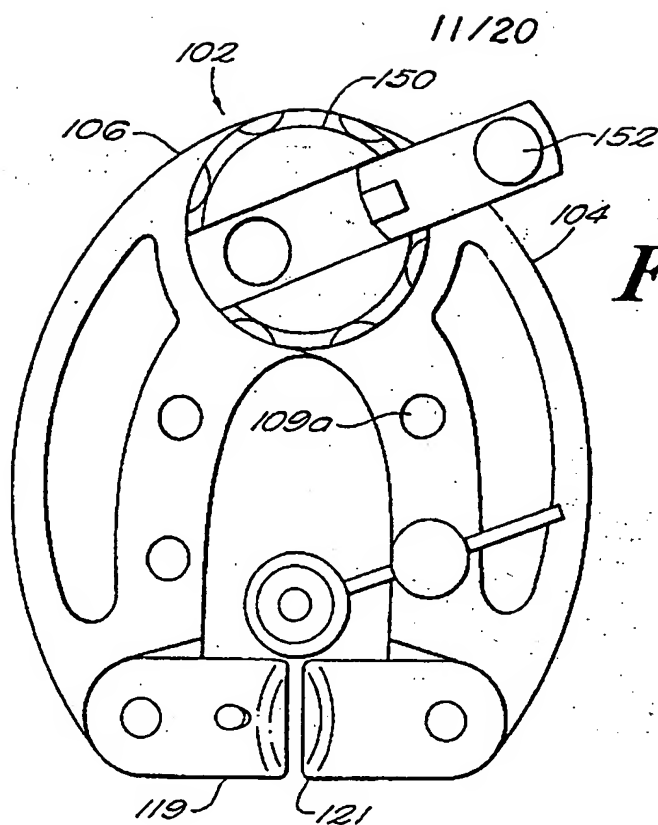


FIG. 11A

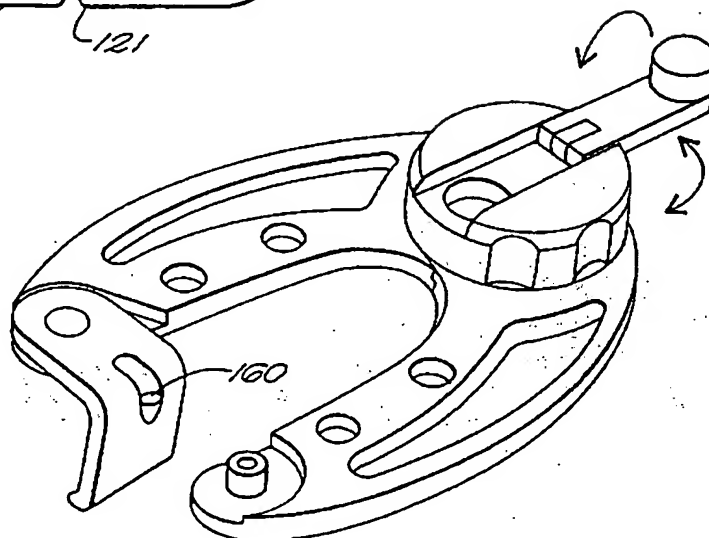


FIG. 11B

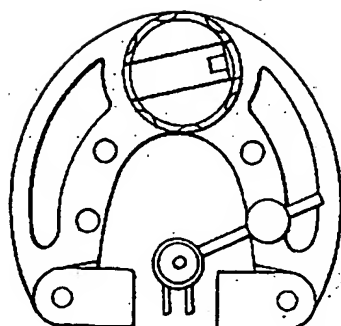
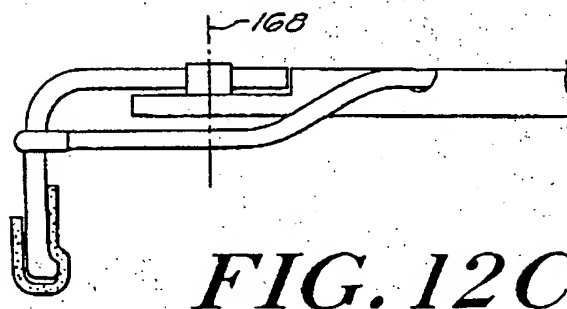
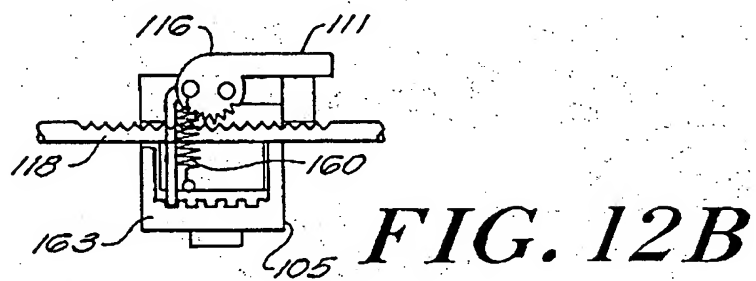
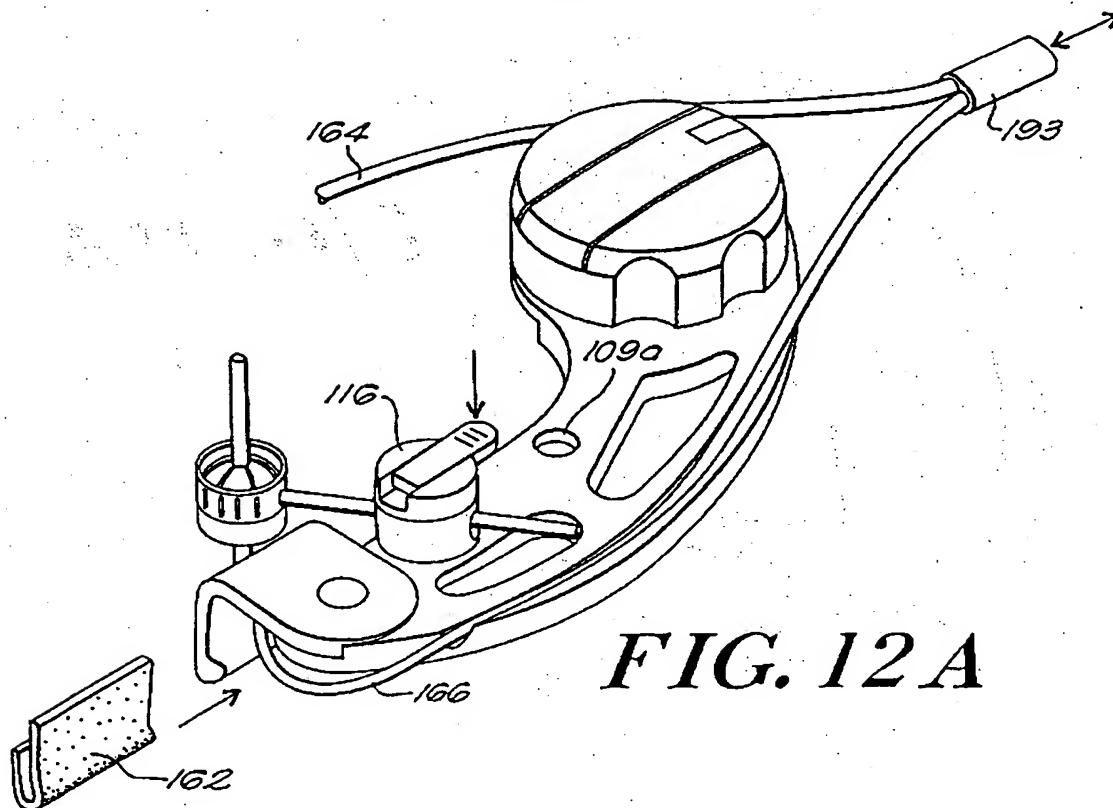
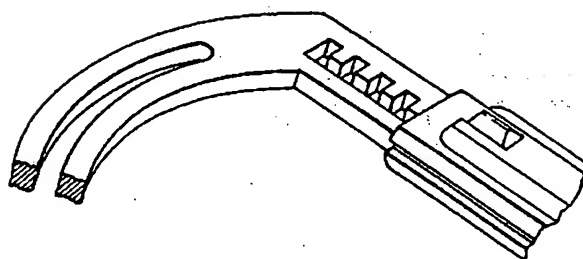
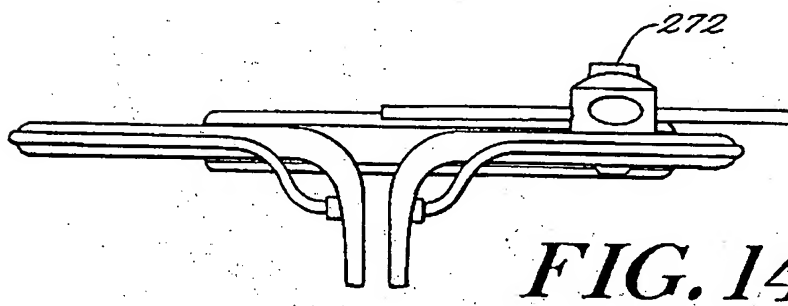
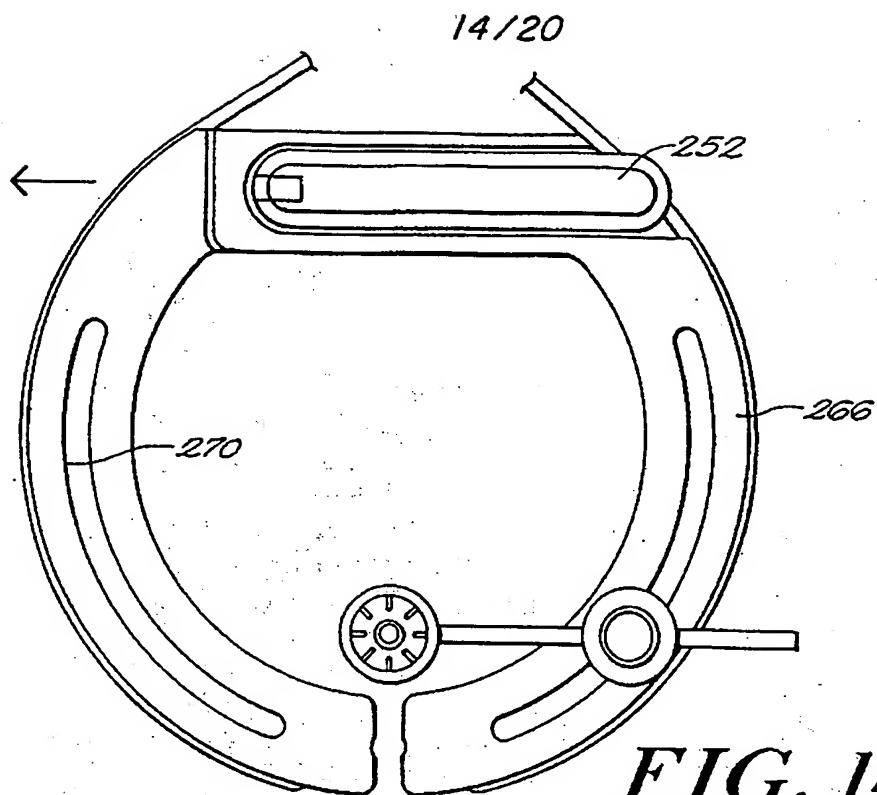


FIG. 11C

12/20





15/20

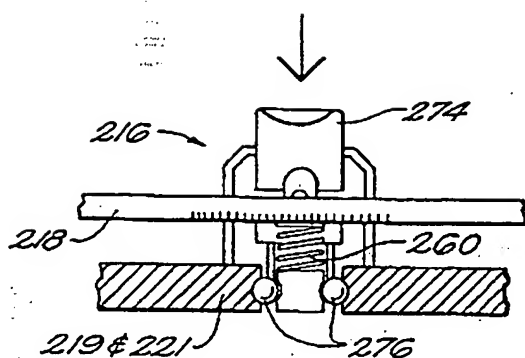


FIG. 15B

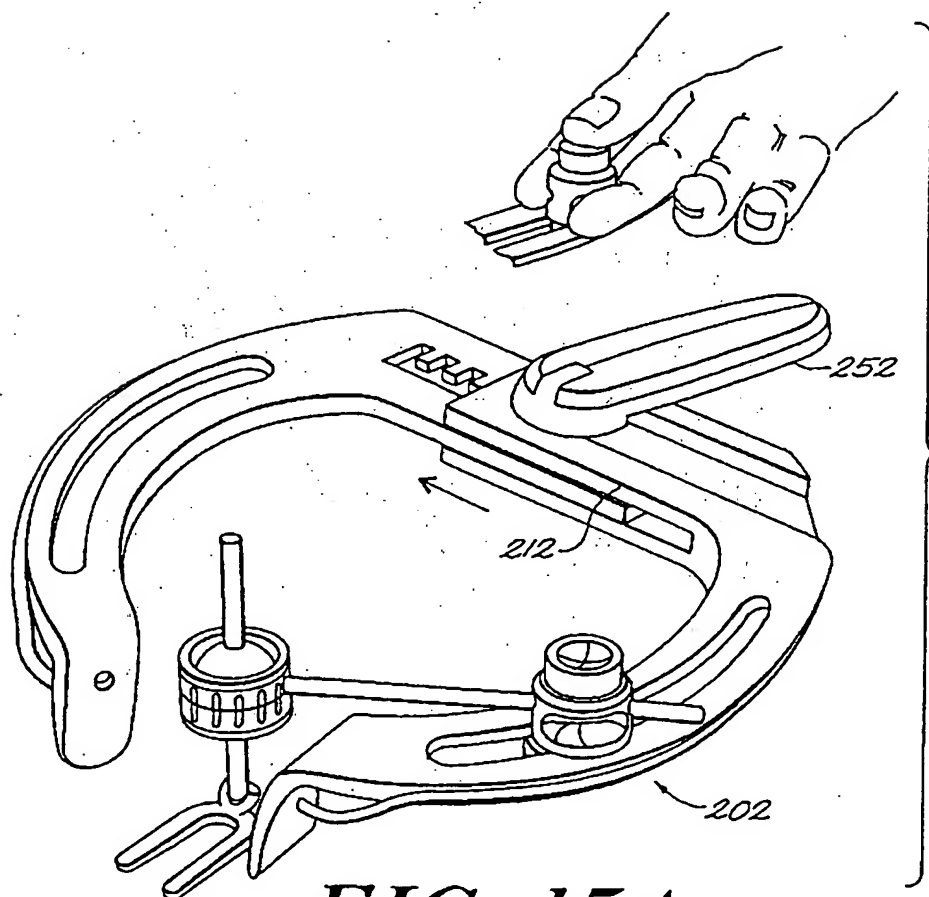


FIG. 15A
SUBSTITUTE SHEET (RULE 26)

16/20

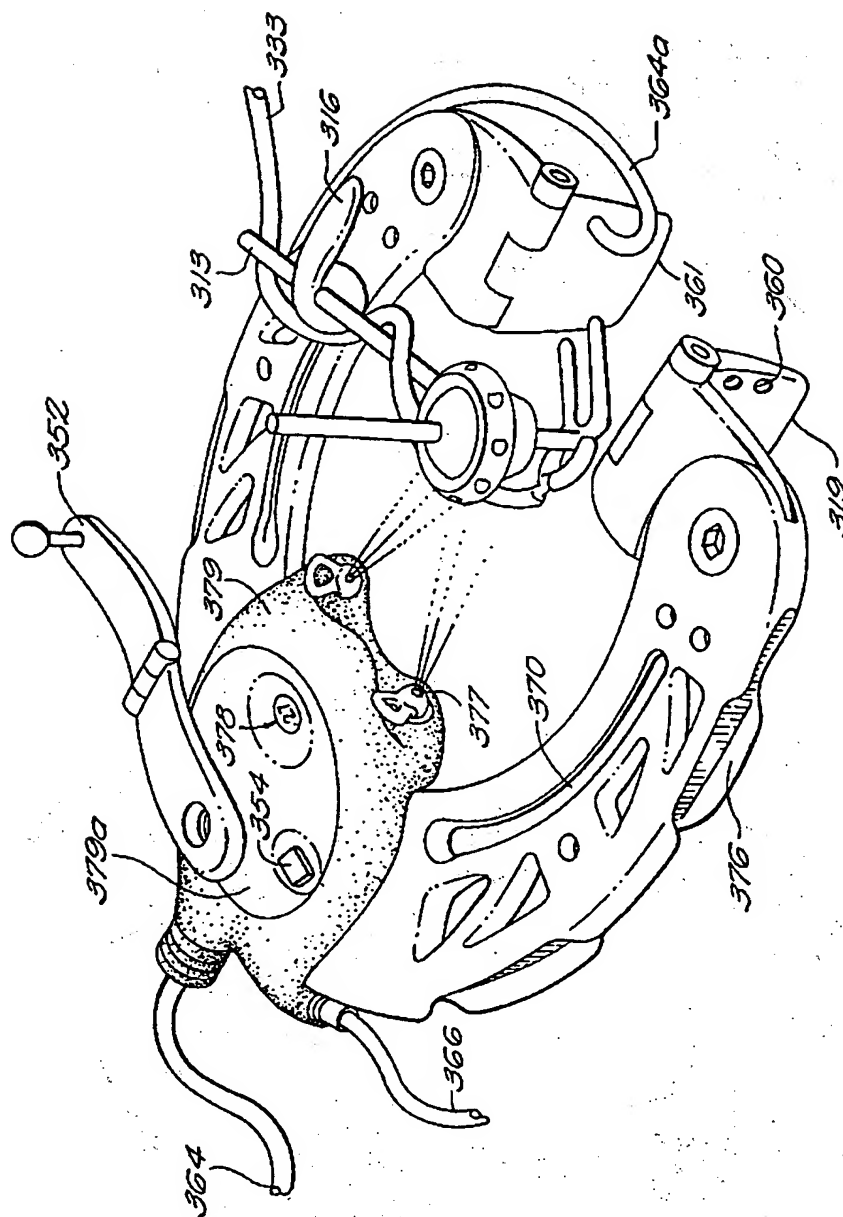


FIG. 16A

17/20

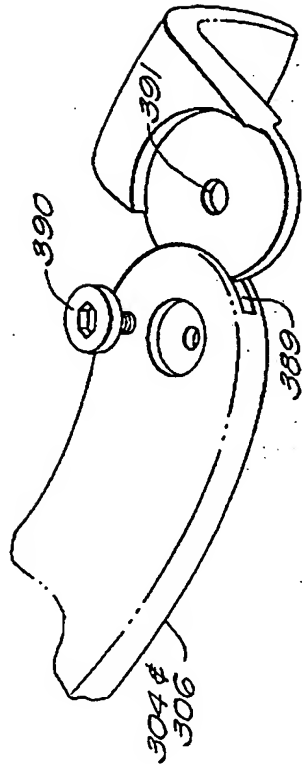
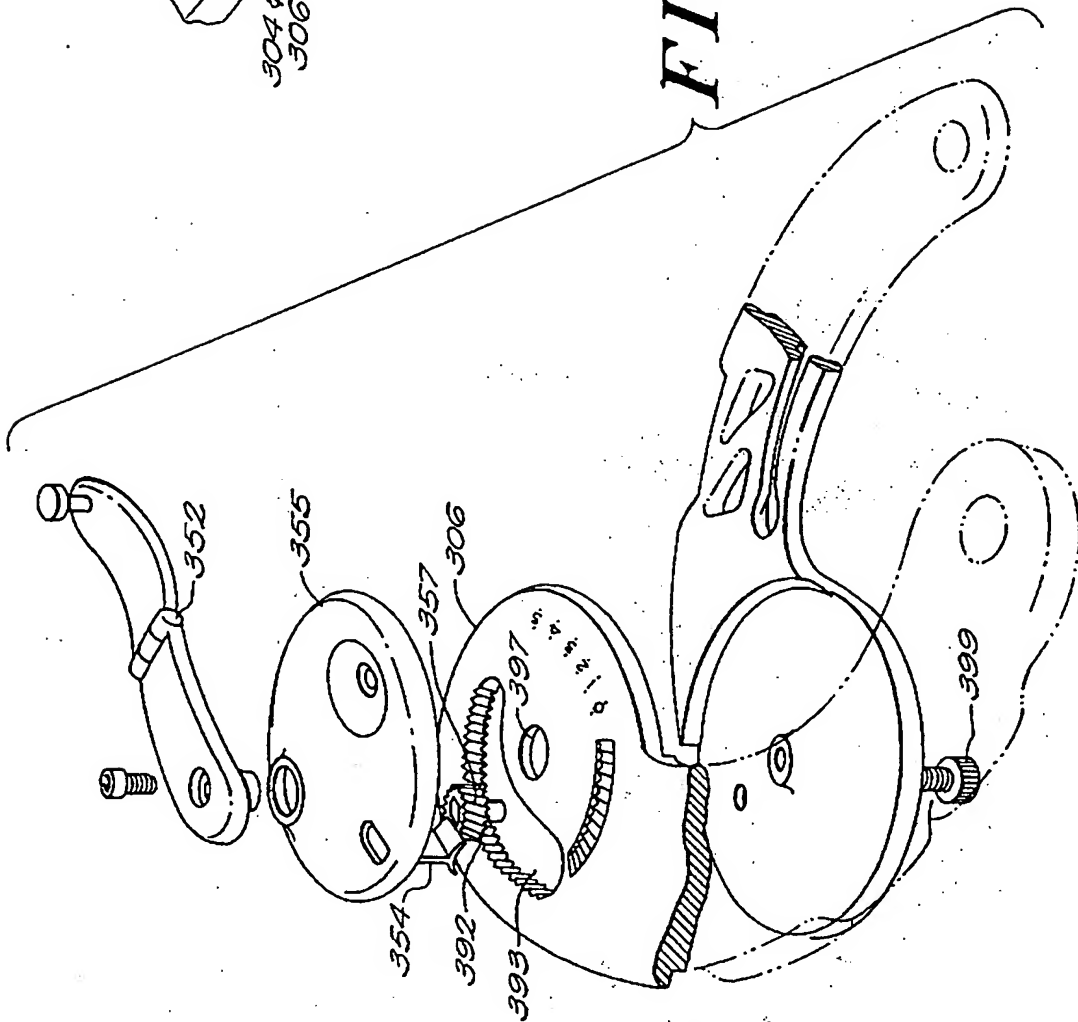


FIG. 16C

FIG. 16B



18/20

FIG. 17A

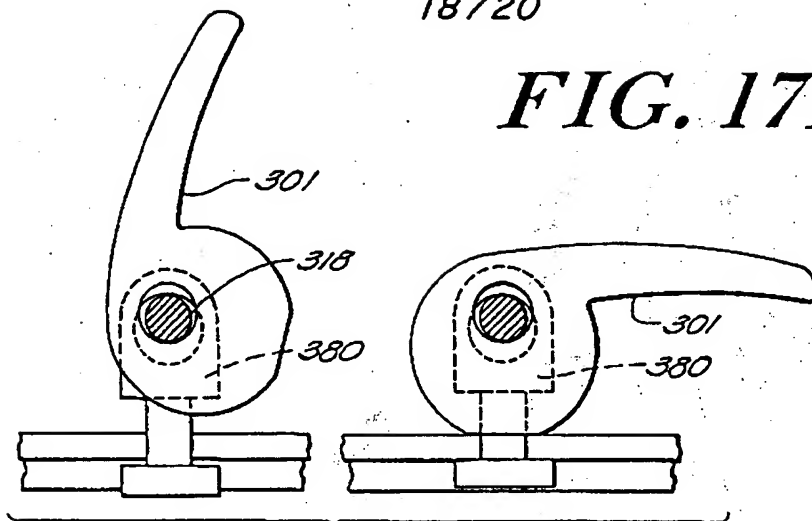


FIG. 17B

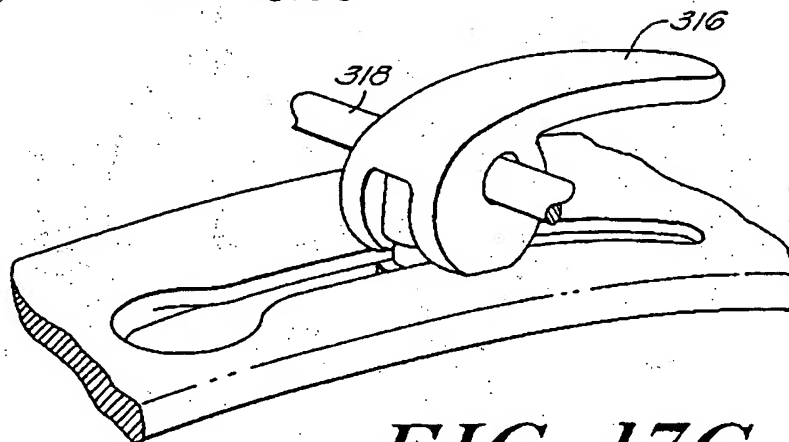
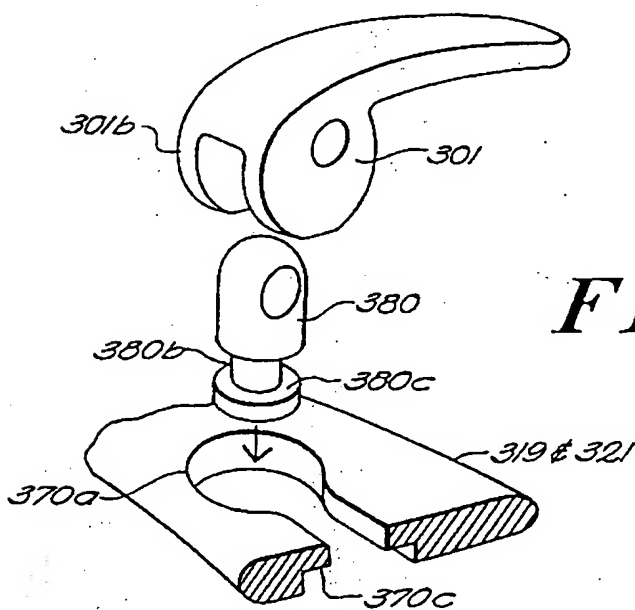


FIG. 17C

19/20

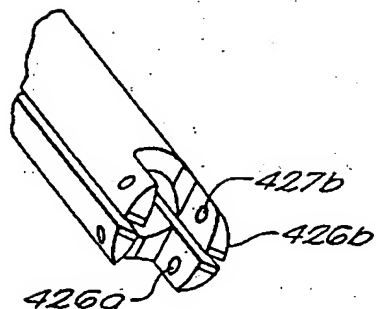


FIG. 18A-1

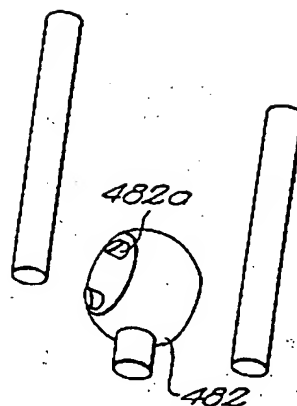


FIG. 18A-2

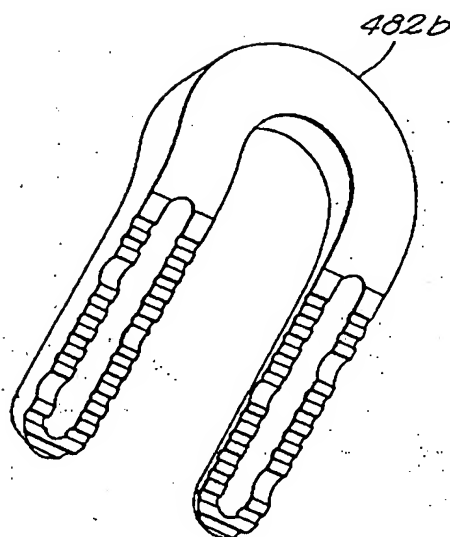


FIG. 18A-3

SUBSTITUTE SHEET (RULE 26)

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 97/23612

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 396 525 A (SHULMAN DAVID H ;BERMAN BARRY R (US)) 7 November 1990	37
A	see abstract; figures 1-4 ---	1,35,36
A	US 5 263 956 A (NOBLES ANTHONY A) 23 November 1993 see abstract; figures 2-4 ---	1-36
A	US 5 133 724 A (WILSON JR ROBERT W ET AL) 28 July 1992 see column 3, line 29 - line 45; figure 1 ---	14,18-26
A	WO 95 15715 A (STANFORD SURGICAL TECHNOLOGIES) 15 June 1995 see page 26, line 7 - page 27, line 20; figures 13-16,25 -----	14,17-31

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 97/23612

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 38-41
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

Intern. Application No
PCT/US 97/23612

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5167223 A	01-12-92	NONE	
US 4573452 A	04-03-86	GB 2180754 A,B	08-04-87
US 4993862 A	19-02-91	NONE	
GB 2218912 A	29-11-89	NONE	
EP 0396525 A	07-11-90	US 4991566 A	12-02-91
		CA 2014230 A	25-10-90
		US 5097820 A	24-03-92
US 5263956 A	23-11-93	NONE	
US 5133724 A	28-07-92	NONE	
WO 9515715 A	15-06-95	US 5571215 A	05-11-96
		AU 1099595 A	27-06-95
		CA 2177490 A	15-06-95
		EP 0732890 A	25-09-96
		JP 9509585 T	30-09-97
		US 5613937 A	25-03-97
		US 5713951 A	03-02-98
		US 5728151 A	17-03-98
		US 5718725 A	17-02-98
		US 5682906 A	04-11-97

**This Page is Inserted by IFW Indexing and Scanning
Operations and is not part of the Official Record**

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- ☐ **BLACK BORDERS**
- ☐ **IMAGE CUT OFF AT TOP, BOTTOM OR SIDES**
- ☐ **FADED TEXT OR DRAWING**
- ☒ **BLURRED OR ILLEGIBLE TEXT OR DRAWING**
- ☐ **SKEWED/SLANTED IMAGES**
- ☐ **COLOR OR BLACK AND WHITE PHOTOGRAPHS**
- ☐ **GRAY SCALE DOCUMENTS**
- ☐ **LINES OR MARKS ON ORIGINAL DOCUMENT**
- ☐ **REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY**
- ☐ **OTHER:** _____

IMAGES ARE BEST AVAILABLE COPY.

As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.

THIS PAGE BLANK (USPTO)